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from: General Secretariat
to: Permanent Representatives Committee/Council
Subject: Proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices
- Outcome of the European Parliament's first reading
(Strasbourg, 21 to 24 October 2013)

I. INTRODUCTION

The Rapporteur, Dr Peter LIESE (EPP - DE), presented a report consisting of 254 amendments (amendments 1-254) on behalf of the Committee on the Environment, Public Health and Food Safety. In addition, the ALDE political group tabled eight amendments (amendments 255-262) and the EPP political group tabled ten amendments (amendments 263-272).

II. DEBATE

The debate, which took place on 22 October 2013, was a joint debate which covered two Ordinary Legislative Procedure proposals:

- the proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices [2012/0267 (COD) / Rapporteur: Dr Peter LIESE (EPP - DE)] - *see section III below for the voting results*; and
- the proposal for a Regulation of the European Parliament and of the Council on Medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 [2012/0266 (COD) / Rapporteur: Mrs Dagmar ROTH-BEHRENDT (S&D - DE)] - *see doc. 14937/13 for the voting results*.

Mrs Dagmar ROTH-BEHRENDT (S&D - DE) opened the debate, which took place on 22 October 2013, and:

- stressed the importance of ensuring high-quality medical devices and promoting the competitiveness of European industry;
- recalled that many hip replacements have proved to be faulty and have had to be removed;
- therefore called for a new and better system to replace the old antiquated system. The new system should include the best possible certification bodies with the best scientific backing;
- stated that there is no need for manufacturers to respond hysterically. They have nothing to fear if they are already producing good-quality products. Four months is not a long time given that product creation and lifespan last for years - but it is sufficient to provide assurance regarding product quality and patient safety;
- expressed her wish for the Commission to speak as much about patient safety as about competitiveness; and
- noted that European doctors are calling for centralised authorisation for high-risk products. The Committee report will not achieve this, but it does make a concrete contribution towards patient safety. For example, there will be unified standards on re-used products and the re-use of some products will not be permitted. It is important to ensure the best possible quality throughout the EU and not just in a few Member States. Manufacturers should be made properly liable.

Dr Peter LIESE (EPP - DE):

- noted that there are problems with diagnostic as well as medical devices;
- recalled that there had been an HIV test on the market for years and with a CE mark - but that this test had in fact been giving false results;
- stressed the need for unannounced inspections;
- stated the EPP political group's support for the strengthening of notified bodies for high-risk products, but argued against introducing central authorisation by EMEA because that would not necessarily improve product safety;
- emphasised the need to ensure continuing innovation, if only for patients' benefit;
- stated that the Committee report struck the right balance between product safety controls and the promotion of innovation;
- called for the abolition of the existing 23 sub-groups. This would increase balance and provide a better overview;
- stressed the important role of reference laboratories;
- noted that DNA tests can have a major impact on patients' lives. Some illnesses can only be treated if diagnosed at an early stage (in some cases only before symptoms appear). Genetic information can permit this early diagnosis. Yet it can also raise psychological, insurance and employment issues. DNA tests must therefore be properly authorised;
- welcomed the acceptance of the principle of informed consent; and
- called for a rapid response from the Council so that the dossier can be politically agreed before the elections.

Commissioner MIMICA:

- referred to the shortcomings in current legislation, which go beyond the breast implant scandal (though that was a case of fraud which no control could have prevented);
- stressed the need for:
 - more clarity for borderline and innovative products;
 - stricter requirements for notified bodies and for their oversight of manufacturers;
 - obligatory unannounced audits; and
 - legislation to restore the trust of patients, consumers and medical professionals in the regulatory system;

- recalled that the Commission had proposed to maintain the current system of self-certification by manufacturers for low-risk products and of notification for medium-risk products. For high-risk products, the Commission had proposed to allow public authorities to take a second look in specific cases (e.g. when the product is particularly innovative or when particular problems had arisen in a product category) - but this was intended to be an exceptional safeguard and the impact assessment had assumed that only around 50 products would be scrutinised per annum. The Committee had proposed changes to the Commission's proposal in this regard. The Commission's proposal could certainly be improved (for example, it may not have made sufficient provision to ensure adequate technical and scientific expertise for scrutiny), but overall the Commission's proposal for the scrutiny procedure to serve as an exceptional safeguard strikes the right balance between patient safety and avoiding unnecessarily burdensome regulation;
- recognised the need for European rules to cover the reprocessing of single-use medical devices. The Commission's proposal would introduce a strict rule on reprocessing based on the latest scientific evidence. It would allow the practice of reprocessing to be developed further, but only under clear and strict conditions - thus allowing health care systems to save money. The Commission would carefully reflect upon the amendments adopted by the plenary to see if they would promote patient protection;
- stated that the Commission would give favourable consideration to amendments intended to strengthen ethical committees, and regarding minors and incapacitated patients. These amendments must be compatible with the proposed regulation on clinical trials on pharmaceuticals;
- stated that the various amendments regarding *in vitro* diagnostics are also acceptable in principle (e.g. regarding in-house exemption, and regarding counselling and informed consent in the field of genetic testing);
- stated that the Commission would consider all amendments with a view to maximising patient and consumer safety, whilst also ensuring that innovation continues to flourish; and
- called for political agreement on the proposal before the end of the Parliament's current term.

Speaking on behalf of the Committee on Employment and Social Affairs, Mrs Edite ESTRELA (S&D - PT):

- emphasised the importance of the safety of health and laboratory workers, as well as of other ancillary workers (e.g. cleaners and laundry workers); and
- stressed the need for correct training in the use of medical devices.

Speaking on behalf of the Committee on the Internal Market and Consumer Protection, Mrs Nora BERRA (EPP - FR):

- welcomed the new opportunity to conduct in-depth reviews of new products on the basis of a European-level database;
- argued that the withdrawal of devices should be left to individual Member States;
- called for collective public monitoring for high-risk devices. Manufacturers need legal predictability; and
- stressed the importance of not placing undue constraints on innovation.

Speaking on behalf of the EPP political group, Mrs Mairead McGUINNESS (EPP - IE):

- regretted the fact that it had required a crisis to trigger the reform process;
- recalled that the Member States and the Commission have conducted 11 joint inspections. Two of these resulted in the temporary suspension of production. Such inspections are clearly worthwhile;
- stressed the need to strengthen notification bodies. Specialist notification bodies are essential for high-risk products;
- called for an additional enhanced level of scrutiny, where products demand this;
- emphasised the need for much tighter post-market surveillance in order to allow quick feedback throughout the system and a rapid response; and
- stated that the reprocessing of medical devices is a very complex issue. Practices vary greatly between different Member States. She asked the Commission to submit a new proposal on this point in the future.

Speaking on behalf of the S&D political group, Mr Gilles PARGNEAUX (S&D - FR):

- stated that he would have liked to provide for systematic, prior and independent evaluation, but that he could accept the compromise contained in the Committee's report as the "least bad" solution;
- stated, with regard to single-use devices, that he was not personally in favour of re-use because of health risks and because there is no proof that they can be re-used. Individual Member States should therefore be granted a derogation on this issue.

Speaking on behalf of the ALDE political group, Mrs Rebecca TAYLOR (ALDE - UK):

- welcomed the workable and more streamlined approach agreed by the Committee on the authorisation of high-risk devices;
- stated that her political group opposed amendments 72 and 271, which would unnecessarily restrict genetic medicine. The Committee's report applied the same approach - which had been designed for testing for life-threatening conditions - to all genetic tests, but this approach is not always appropriate. Furthermore, there is no legal basis for the EU to regulate national medical practice. Her political group had therefore tabled amendments 255 and 256 in an attempt to address the issue, but without damaging developments in this area; and
- expressed her political group's opposition to amendments 42, 68 and 205, which would make all sexual health tests available on prescription only. By contrast, the British and French governments aim to make such tests as easily available as possible to all. Her political group therefore supported amendment 268 as an alternative.

Speaking on behalf of the Greens/EFA political group, Mrs Margrete AUKEN (Greens/EFA - DK):

- welcomed the emphasis to be placed on ethical committees and on qualified counselling for DNA tests; and
- whilst noting the calls to strengthen approval procedures, argued that transparency would be crucial to ensuring a safe system.

Speaking on behalf of the EUL/NGL political group, Mrs Alda SOUSA (EUL/NGL - PT) stressed the need for a uniform authorisation procedure throughout the EU.

Speaking on behalf of the EFD political group, Mr Derek CLARK (EFD - UK) stressed the adverse impact of excessive regulation on SMEs and on employment. Such regulation benefits only large manufacturers.

Mrs Jolanta HIBNER (EPP - PL) stressed the need for manufacturers of medical devices to purchase insurance against faulty product liability.

Mrs Christel SCHALDEMOSE (S&D - DK):

- stated that the Committee's report would not close all loop-holes, because the right-wing political groups had given too much priority to manufacturers' interests. The proposal is therefore a step in the right direction, but not a milestone; and
- agreed with Mrs Auken on the importance of transparency, but argued that the proposed decentralised approach would work against this.

Mr Holger KRAHMER (ALDE - DE):

- stressed the need to ensure that the proposed legislation can be implemented in practice. The Committee's report is probably not practicable. It may well be necessary to extend the authorisation periods. The report's amendments may not necessarily improve product safety; and
- stated that only a tiny percentage of manufacturers in this sector have a criminal intent. It is not appropriate to give undue consideration to this tiny percentage when legislating for the entire sector.

Mrs Michèle RIVASI (Greens/EFA - FR)

- stressed the fact that there has been negligence in the past. Her political group had called for prior authorisation. She regretted the fact that the Commission had not included this in its proposal;
- argued that the proposed special notification bodies for high-risk products are the bare minimum; and
- supported a ban on all carcinogens being used in medical devices.

Mr Richard SEEBER (EPP - AT):

- supported the Committee's report as a whole. Political groups may disagree on details, but there is general cross-party agreement on the broad issues;
- argued that central authorisation will not prevent corruption. Central authorities are just as error-prone as decentralised authorities;
- stated that the EU's current system allows for flexibility. This should be maintained; and
- whilst conceding that jobs do not justify everything, emphasised the fact that this sector of industry is highly innovative and economically valuable.

Mr Andrés PERELLÓ RODRÍGUEZ (S&D - ES):

- stated that the breast implants case showed that fraud can and does happen. Such fraud needs to be addressed; and
- emphasised the need for transparency and traceability.

Mr Milan CABRNOCH (ECR - CZ):

- stressed the need to respect the subsidiarity principle, to avoid unnecessary costs, and to avoid constraints on product innovation; and
- noted the concerns of some experts that some forms of medical care will no longer be available to patients.

Mrs Françoise GROSSETÊTE (EPP - FR):

- stressed the need to close loopholes in existing legislation which have allowed fraud to take place. Proper sanctions should be introduced for infringements;
- argued that re-use of devices should not be permitted; and
- called for medical devices to be regulated as strictly as medicinal drugs.

Mr Thomas ULMER (EPP - DE) stated that he was content with the compromise contained in the Committee's report, but that it would necessary to review the situation in a few years.

Commissioner MIMICA once more took the floor and:

- stressed the need to strike the right balance between patient needs and industry interests (especially those of SMEs), but stressed the fact that there should be no compromise on patient safety;
- suggested that it might be appropriate in the future to shift the focus of scrutiny from pre-market to post-market scrutiny based on data; and
- expressed his abiding confidence that a political agreement can be reached by the end of the Parliament's current term. All parties will need to compromise. He welcomed the Lithuanian presidency's commitment to enter into negotiations with the Parliament before the end of 2013.

Mrs Dagmar ROTH-BEHRENDT once more took the floor and:

- called on the plenary to support all the Committee's compromise amendments, though she also warned that some amendments would unduly dilute the proposal;
- stated that four months is not a long time for an authorisation procedure;
- agreed that re-use can be dangerous, but argued that a ban on re-use should be limited to products which are authorised as single-use products; and
- called on the Council to reach its initial negotiating mandate as soon as possible in order to permit an early start to negotiations.

Dr Peter LIESE (EPP - DE) once more took the floor and:

- recalled that there had been a suggestion that a requirement for informed consent on genetic tests would prevent certain medical practices. There had been long discussion, but he believed that the Committee's approach is practicable. He therefore opposed the amendments of the ALDE political group; and
- noted that the Committee's amendments already require approval by an ethics committee. There is therefore no need for further amendments on this point.

III. VOTE

When it voted on 22 October 2013, the Parliament voted to adopt 342 amendments to the Commission's proposal (amendments 1-22, 24-35, 38-41, 43-73, 75-80, 82-84, 86-113, 118, 120-161, 165, 167-175, 177-240, 243-268, 271-340, 343-344, 347, 354-355, 357-361, 363-364, 366-374 and 377-379), but then postponed the vote on the legislative resolution to a later session - thereby not bringing the Parliament's first reading to a close. The proposal was instead referred back to the Committee on the Environment, Public Health and Food Safety, pursuant to Rule 57(2) of the European Parliament's Rules of Procedure.

The adopted amendments are set out in the Annex.

P7_TA-PROV(2013)0427

In vitro diagnostic medical devices ***I

Amendments adopted by the European Parliament on 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices (COM(2012)0541 – C7-0317/2012 – 2012/0267(COD))¹

(Ordinary legislative procedure: first reading)

Amendment 1

Proposal for a regulation

Recital 2

Text proposed by the Commission

(2) This Regulation aims to ensure the functioning of the internal market as regards in vitro diagnostic medical devices, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for devices to meet common safety concerns as regards those products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union, this Regulation harmonises the rules for the placing on the market and putting into service of in vitro diagnostic medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) *of the Treaty on the Functioning of the European Union*, this Regulation sets high standards of quality and safety for those devices by ensuring, among other things, that data generated in clinical performance studies is reliable and robust and that the safety of subjects

Amendment

(2) This Regulation aims to ensure the functioning of the internal market as regards in vitro diagnostic medical devices, taking as a base a high level of protection of health *for patients, users and operators*. At the same time, this Regulation sets high standards of quality and safety for devices to meet common safety concerns as regards those products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (*TFEU*), this Regulation harmonises the rules for the placing on the market and putting into service of in vitro diagnostic medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) *TFEU*, this Regulation sets high standards of quality and safety for those devices by ensuring, among other things, that data generated in clinical performance studies is reliable and robust and that the safety of subjects participating in clinical

¹ The matter was referred back to the committee responsible for reconsideration pursuant to Rule 57(2), second subparagraph (A7-0327/2013).

participating in clinical performance studies is protected.

performance studies is protected.

Amendment 2

Proposal for a regulation

Recital 3

Text proposed by the Commission

(3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, **risk classification**, conformity assessment procedures, clinical **evidence**, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding in vitro diagnostic medical devices should be introduced to improve health and safety.

Amendment

(3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical **investigations and clinical evaluation**, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding devices should be introduced, to improve health and safety **for health professionals, patients, users and operators, including in the waste disposal chain**.

Amendment 3

Proposal for a regulation

Recital 5

Text proposed by the Commission

(5) There are specific features of in vitro diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the in vitro diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned.

Amendment

(5) There are specific features of in vitro diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the in vitro diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned **without compromising the need for innovation in the Union**.

Amendment 4

Proposal for a regulation Recital 5 a (new)

Text proposed by the Commission

Amendment

(5a) The high number of small and medium enterprises (SMEs) active in the area of in-vitro diagnostic medical devices should be taken into account when regulating that area, while avoiding the creation of health and safety risks.

Amendment 5

Proposal for a regulation Recital 7 a (new)

Text proposed by the Commission

Amendment

(7a) A multidisciplinary Medical Device Advisory Committee (MDAC) composed of experts and representatives of the relevant stakeholders should be set up to provide scientific advice to the Commission, the Medical Device Coordination Group (MDCG) and Member States on issues of medical technology, regulatory status of devices and other aspects of implementation of this Regulation as necessary.

Amendment 6

Proposal for a regulation Recital 8

Text proposed by the Commission

Amendment

(8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. If necessary, the Commission may decide, on a case-by-case basis, whether or not a product falls within the definition of an in vitro diagnostic medical device or of an accessory to an in vitro diagnostic medical device.

(8) In order to ensure consistent classification across all Member States, particularly with regard to borderline cases, it should be the responsibility of the Commission, having consulted the MDCG and the MDAC, to decide on a case-by-case basis whether or not a product or groups of products fall within the scope of this Regulation. Member States should also have the possibility to request the

Commission to take a decision on the appropriate regulatory status of a product, or category or group of products.

Amendment 7

Proposal for a regulation

Recital 9 a (new)

Text proposed by the Commission

Amendment

(9a) In the case of urgent or unmet medical needs for patients, such as emerging pathogens and rare diseases, single health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby addressing, within a non-commercial and flexible framework, specific needs which cannot be met by an available CE-marked device.

Amendment 8

Proposal for a regulation

Recital 9 b (new)

Text proposed by the Commission

Amendment

(9b) However, devices which are manufactured within non-health-institution laboratories and put into service without being placed onto the market should be subject to this Regulation.

Amendment 9

Proposal for a regulation

Recital 13 a (new)

Text proposed by the Commission

Amendment

(13a) Directive 2013/35/EU of the European Parliament and of the Council¹ should be the reference text for ensuring that people working in the vicinity of magnetic resonance imaging equipment when it is in operation are properly protected.

¹ *Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC (OJ L 197,29.6.2013, p. 1).*

Amendment 10

Proposal for a regulation Recital 22

Text proposed by the Commission

(22) It should be ensured that supervision and control of the manufacture of *in vitro* diagnostic medical devices is carried out within the manufacturer's organisation by a person who fulfils minimum conditions of qualification.

Amendment

(22) It should be ensured that supervision and control of the manufacture of *in vitro* diagnostic medical devices is carried out within the manufacturer's organisation by a person who fulfils minimum conditions of qualification. ***In addition to regulatory compliance, that person could also be responsible for compliance in other fields such as manufacturing processes and quality assessment. The required qualifications of the person responsible for the regulatory compliance should be without prejudice to national provisions regarding professional qualifications, in particular for manufacturers of custom-made devices where such requirements could be met through different educational and professional training systems at national level.***

Amendment 11

Proposal for a regulation Recital 25 a (new)

Text proposed by the Commission

Amendment

(25a) To ensure that patients harmed are compensated for any damage and associated treatment as a result of a faulty *in vitro* diagnostic medical device, that the risk of

damage as well as the risk of the manufacturer's insolvency are not shifted to patients harmed by a faulty in vitro diagnostic medical device, manufacturers should be obliged to take liability insurance with sufficient minimum coverage.

Amendment 12

Proposal for a regulation

Recital 26

Text proposed by the Commission

(26) In vitro diagnostic medical devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation.

Amendment

(26) In vitro diagnostic medical devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation. ***However Member States should be allowed to decide whether to restrict the use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation.***

Amendment 13

Proposal for a regulation

Recital 27

Text proposed by the Commission

(27) The traceability of in vitro diagnostic medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of in vitro diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also

Amendment

(27) The traceability of in vitro diagnostic medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of in vitro diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also

improve *purchase-policy and stock-management by hospitals*.

improve *purchasing and waste disposal policies and hospitals', wholesalers' and pharmacists' management of stock and, where possible, be compatible with other authentication systems already in place in those settings*.

Amendment 14

Proposal for a regulation

Recital 28

Text proposed by the Commission

(28) Transparency and *better* information are essential to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

Amendment

(28) Transparency and *adequate access to information, appropriately presented for the intended user*, are essential to empower patients and healthcare professionals *and all others concerned*, and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

Amendment 15

Proposal for a regulation

Recital 29

Text proposed by the Commission

(29) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding in vitro diagnostic medical devices on the market and the relevant economic operators, certificates, interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the

Amendment

(29) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding in vitro diagnostic medical devices on the market and the relevant economic operators, certificates, interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, *via better access to information for the public and healthcare professionals*, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the

coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) by further developing the databank set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.

Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) by further developing the databank set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.

Amendment 16

Proposal for a regulation Recital 30

Text proposed by the Commission

(30) Eudamed's electronic systems ***regarding devices on the market, the relevant economic operators and certificates*** should enable the public to be adequately informed about devices on the Union market. The electronic system on clinical performance studies should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, in this case, to report serious adverse events. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by national competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

Amendment

(30) Eudamed's electronic systems should enable the public ***and healthcare professionals*** to be adequately informed about devices on the Union market. ***Adequate levels of access for the public and healthcare professionals to those parts of Eudamed's electronic systems which provide key information on in vitro diagnostic medical devices that may pose a risk to public health and safety is essential. Where such access is limited, it should be possible, upon a reasoned request, to disclose the existing information on in vitro diagnostic medical devices, unless the limitation of access is justified on grounds of confidentiality.*** The electronic system on clinical performance studies should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, in this case, to report serious adverse events. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by national competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information

between competent authorities. ***A regular overview of vigilance and market surveillance information should be made available to healthcare professionals and the public.***

Amendment 17

Proposal for a regulation Recital 32

Text proposed by the Commission

(32) For high-risk *in vitro* diagnostic medical devices, manufacturers should ***summarise the main*** safety and performance aspects of the device and the outcome of the clinical evaluation ***in a document that*** should be publicly available.

Amendment

(32) For high-risk *in vitro* diagnostic medical devices, ***in the interests of increased transparency,*** manufacturers should ***draw up a report on the*** safety and performance aspects of the device and the outcome of the clinical evaluation. ***A summary of the safety and performance report*** should be publicly available ***via Eudamed.***

Amendment 18

Proposal for a regulation Recital 32 a (new)

Text proposed by the Commission

Amendment

(32a) According to the policy of the European Medicines Agency (EMA) on access to documents, the EMA releases documents submitted as part of applications for marketing authorisation for medicinal products, including clinical trial reports, on request once the decision-making process for the medicinal product in question has been completed. Corresponding standards on transparency and access to documents should be upheld and reinforced for high-risk in vitro diagnostic medical devices, in particular as they are not subject to pre-market approval. For the purposes of this Regulation, in general the data included in clinical performance studies should not be considered commercially sensitive provided that compliance of a device with the applicable requirements has been demonstrated following the applicable

conformity assessment procedure. This should be without prejudice to intellectual property rights concerning the use by other manufacturers of data from clinical performance studies by the manufacturer.

Amendment 19

Proposal for a regulation

Recital 33

Text proposed by the Commission

(33) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

Amendment

(33) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, **and where applicable by EMA**, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

Amendment 20

Proposal for a regulation

Recital 35

Text proposed by the Commission

(35) For high risk in vitro diagnostic medical devices, authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, on scientifically valid grounds, to scrutinise the preliminary assessment conducted by notified bodies, in particular regarding devices for which no common technical specifications exist, devices which are novel or for which a novel technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent

Amendment

deleted

authority of his intention to file an application for conformity assessment for a high risk in vitro diagnostic medical device before submitting the application to the notified body.

Amendment 262

Proposal for a regulation Recital 40 a (new)

Text proposed by the Commission

Amendment

(40a) Clinical expertise and specialist product knowledge within notified bodies, Special notified bodies and the Medical Device Coordination Group should be appropriate for the specifications of in vitro diagnostic medical devices. Clinical experts should have expertise in clinical interpretation of in vitro diagnostic results, metrology and Good Laboratory Practice. Clinical experts and product specialists should have expertise in fields such as virology, haematology, clinical analysis, genetics.

Amendment 22

Proposal for a regulation Recital 43 a (new)

Text proposed by the Commission

Amendment

43a. The Declaration of Helsinki of the World Medical Association¹ states in Article 15 that "the research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins." Interventional clinical performance studies and other clinical performance studies involving risk for the subject should only be allowed after assessment and approval by an ethics committee. The reporting Member State and the other concerned Member States need to organise themselves in a way that the competent authority concerned receives approval by an ethics committee on the clinical performance study

protocol.

¹ WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and lastly amended by the 59th WMA General Assembly, Seoul, Korea, October 2008

[http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=\[page\]/\[toPage\]](http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=[page]/[toPage])

Amendment 23

Proposal for a regulation Recital 44 a (new)

Text proposed by the Commission

Amendment

(44a) For the sake of transparency, sponsors should submit the results of a clinical performance study together with a 'layperson' summary within the deadlines specified by the regulation. The Commission should be empowered to adopt delegated acts on the preparation of the layperson's summary and the communication of the clinical performance study report. The Commission should provide guidelines for managing, and facilitating the sharing of, raw data from all clinical performance studies.

Amendment 24

Proposal for a regulation Recital 45

Text proposed by the Commission

Amendment

(45) Sponsors of interventional clinical performance studies and other clinical performance studies involving risks for the subjects to be conducted in more than one Member State should be given the possibility to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the

(45) Sponsors of interventional clinical performance studies and other clinical performance studies involving risks for the subjects to be conducted in more than one Member State should be given the possibility to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the

assessment of the health and safety related aspects of the device for performance evaluation and of the scientific design of the clinical performance study to be conducted in several Member States, such single application should facilitate the coordination between the Member States under the direction of a coordinating Member State. ***The coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical performance study, including informed consent.*** Each Member State should retain the ultimate responsibility for deciding whether the clinical performance study may be conducted on its territory.

assessment of the health and safety related aspects of the device for performance evaluation and of the scientific design of the clinical performance study to be conducted in several Member States, such single application should facilitate the coordination between the Member States under the direction of a coordinating Member State. Each Member State should retain the ultimate responsibility for deciding whether the clinical performance study may be conducted on its territory.

Amendment 25

Proposal for a regulation Recital 45a (new)

Text proposed by the Commission

Amendment

(45a) Strict rules for persons unable to give informed consent such as children and incapacitated persons should be established at the same level as in Directive 2001/20/EC of the European Parliament and of the Council¹.

¹ ***Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).***

Amendment 26

Proposal for a regulation Recital 48

Text proposed by the Commission

Amendment

(48) In order to better protect health and

(48) In order to better protect health and

safety regarding devices on the market, the vigilance system for in vitro diagnostic medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

safety regarding devices on the market, the vigilance system for in vitro diagnostic medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions ***within and outside the Union.***

Amendment 27

Proposal for a regulation Recital 49

Text proposed by the Commission

(49) Healthcare professionals and patients should be empowered to report ***suspected serious*** incidents at national level using harmonised formats. ***The*** national competent authorities should inform manufacturers and ***share*** the information ***with their peers*** when they confirm that ***a serious*** incident has occurred ***in order to minimise recurrence of those incidents.***

Amendment

(49) ***Member States should take all necessary measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents.*** Healthcare professionals, ***users*** and patients should be empowered ***and enabled*** to report such incidents at national level using harmonised formats ***and guaranteeing anonymity, where appropriate. In order to minimise the recurrence of such incidents, the*** national competent authorities should inform manufacturers, ***and, if appropriate, their subsidiaries and sub-contractors,*** and ***report*** the information ***via the respective electronic system in Eudamed*** when they confirm that ***an*** incident has occurred.

Amendment 28

Proposal for a regulation Recital 53

Text proposed by the Commission

(53) The Member States ***shall*** levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies.

Amendment

(53) The Member States ***should*** levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies. ***These fees should be comparable across Member States and should be made public.***

Amendment 29

Proposal for a regulation Recital 54

Text proposed by the Commission

(54) Whilst this Regulation should not affect the right of the Member States to levy fees for activities at national level, Member States should inform the Commission and the other Member States before they adopt the level and structure of the fees to ensure transparency.

Amendment

(54) Whilst this Regulation should not affect the right of the Member States to levy fees for activities at national level, Member States should inform the Commission and the other Member States before they adopt the **comparable** level and structure of the fees to ensure transparency.

Amendment 30

Proposal for a regulation Recital 54 a (new)

Text proposed by the Commission

Amendment

(54a) Member States should adopt provisions on standard fees for notified bodies, which should be comparable across Member States. The Commission should provide guidelines to facilitate the comparability of those fees. Member States should transmit their list of standard fees to the Commission and ensure that the notified bodies registered on their territory make the lists of standard fees for their conformity assessment activities publicly available.

Amendment 31

Proposal for a regulation Recital 55

Text proposed by the Commission

(55) ***An expert committee, the Medical Device Coordination Group (MDCG)***, composed of persons designated by the Member States, based on their role and expertise in the field of medical devices and in vitro diagnostic medical devices, should be established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) [Ref. of

Amendment

(55) A MDCG, composed of persons designated by the Member States, based on their role and expertise in the field of medical devices and in vitro diagnostic medical devices, should be established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices to

future Regulation on medical devices] on medical devices to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation.

fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. ***Prior to taking up their duties, members of the MDCG should make available a declaration of commitment and a declaration of interests indicating either the absence of any interests which could be considered prejudicial to their independence or any direct or indirect interests which could be prejudicial to their independence. Those declarations should be verified by the Commission.***

Amendment 32

Proposal for a regulation Recital 59

Text proposed by the Commission

(59) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.

Amendment

(59) This Regulation respects the fundamental rights and observes the principles recognized in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, ***the principle of free and informed consent of the person concerned***, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property, ***as well as the European Convention on Human Rights and Biomedicine as well as the Additional Protocol to that Convention concerning Genetic Testing for Health Purposes***. This Regulation should be applied by the Member States in accordance with those rights and principles.

Amendment 33

Proposal for a regulation Recital 59 a (new)

Text proposed by the Commission

Amendment

(59a) Clear rules on the application of DNA tests are important. It is however advisable to regulate only on some basic elements and leave room for the Member States for more specific regulation in this area. Member States should for example regulate, that all devices providing an indication of a genetic disease which develops in adulthood or affects family planning may not be used on minors unless preventive treatment is available

Amendment 34

Proposal for a regulation Recital 59 b (new)

Text proposed by the Commission

Amendment

(59b) While genetic counselling should be mandatory in specific cases it should not be mandatory in cases where a diagnosis of a patient already suffering from a disease is confirmed by a genetic test or where a companion diagnostic is used.

Amendment 35

Proposal for a regulation Recital 59 c (new)

Text proposed by the Commission

Amendment

(59c) This Regulation is in keeping with the United Nations Convention on the Rights of Persons with Disabilities of 13 December 2006, ratified by the European Union on 23 December 2010, pursuant to which the signatories commit themselves, in particular, to promote, protect and guarantee the full and equal exercise of all human rights and basic freedoms by all persons with disabilities and to promote the respect of their

inherent dignity, inter alia by raising awareness about the abilities of disabled persons and the contribution they make.

Amendment 270

Proposal for a regulation

Recital 59 d (new)

Text proposed by the Commission

Amendment

59d. Whereas, in view of the need to protect the integrity of the human person during the sampling, collection and use of substances derived from the human body, it is appropriate to apply the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine.

Amendment 36

Proposal for a regulation

Recital 60

Text proposed by the Commission

Amendment

(60) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect ***of the adaptation to technical progress of the general safety and performance requirements, of the elements to be addressed in the technical documentation, of the minimum content of the EU declaration of conformity and of the certificates issued by notified bodies***, of the minimum requirements to be met by notified bodies, of the classification rules, ***of the conformity assessment procedures***, and of the documentation to be submitted for the approval of clinical performance studies; the establishment of the UDI system; the information to be submitted for the registration of *in vitro* diagnostic medical devices and certain economic operators; the level and structure

(60) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the minimum requirements to be met by notified bodies, of the classification rules and of the documentation to be submitted for the approval of clinical performance studies; the establishment of the UDI system; the information to be submitted for the registration of *in vitro* diagnostic medical devices and certain economic operators; the level and structure of fees for the designation and monitoring of notified bodies; the publicly available information in respect of clinical performance studies; the adoption of preventive health protection measures at EU level; and the tasks of and criteria for European Union reference laboratories and the level and

of fees for the designation and monitoring of notified bodies; the publicly available information in respect of clinical performance studies; the adoption of preventive health protection measures at EU level; and the tasks of and criteria for European Union reference laboratories and the level and structure of fees for scientific opinions delivered by them. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

structure of fees for scientific opinions delivered by them. **However, basic aspects elements of this Regulation such as general safety and performance requirements, elements to be addressed in technical documentation, the minimum content of the Union declaration of conformity, amending or supplementing the conformity assessment procedures, should only be amended through the ordinary legislative procedure.** It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Amendment 37

Proposal for a regulation Recital 64

Text proposed by the Commission

(64) To allow economic operators, **notified bodies, Member States and the Commission** to adapt to the changes introduced by this Regulation, it is appropriate to provide for a sufficient transitional period **for that adaptation and for the** organisational arrangements **to be taken for its proper application**. It is particularly important that **by the date of application**, a sufficient number of notified bodies **are designated** in accordance with the new requirements to avoid any shortage of *in vitro* diagnostic medical devices on the market.

Amendment

(64) To allow economic operators, **especially SMEs**, to adapt to the changes introduced by this Regulation **and to ensure its proper application**, it is appropriate to provide for a sufficient transitional period **to allow for** organisational arrangements **to be made**. **However, parts of the Regulation that concern Member States and the Commission should be implemented as soon as possible**. It is particularly important that a sufficient number of notified bodies **is designated** in accordance with the new requirements, **as soon as possible**, to avoid any shortage of *in-vitro* diagnostics medical devices on the market.

Amendment 38

Proposal for a regulation

Recital 65

Text proposed by the Commission

(65) In order to ensure a smooth transition to the registration of in vitro diagnostic medical devices, ***of relevant economic operators and of certificates, the obligation to submit the relevant information to the electronic systems put in place by this Regulation at Union level should become fully effective only 18 months after the date of application of this Regulation. During this transitional period, Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC should remain in force. However,*** economic operators and notified bodies who register in the relevant electronic systems provided for at Union level should be considered in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directive to avoid multiple registrations.

Amendment

(65) In order to ensure a smooth transition to the registration of in vitro diagnostic medical devices the electronic systems put in place by this Regulation at Union level should become ***operational as soon as possible***. Economic operators and notified bodies who register in the relevant electronic systems provided for at Union level should be considered in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directive to avoid multiple registrations.

Amendment 39

Proposal for a regulation

Recital 67 a (new)

Text proposed by the Commission

Amendment

(67 a) It is a long standing policy of the Union not to interfere with national policy allowing, prohibiting or limiting at national level ethically controversial technologies, such as preimplantation genetic testing. This Regulation should not interfere with this principle, and the decision to allow, prohibit or restrict such technologies should therefore remain at national level. Where a Member State allows such technologies whether with or without restriction, the standards laid down in this Regulation should apply.

Amendment 272

Proposal for a regulation Recital 67 b (new)

Text proposed by the Commission

Amendment

(67b) Although internationally certified reference materials and materials used for external quality assessment schemes are not covered by this Directive, calibrators and control materials needed by the user to establish or verify performances of devices are in vitro diagnostic medical devices.

Amendment 268

Proposal for a regulation Article 1 – paragraph 6

Text proposed by the Commission

Amendment

6. This Regulation shall not affect national laws which require that certain devices may only be supplied on a medical prescription.

6. This Regulation ***provides that certain devices may only be supplied on a medical prescription but*** it shall not affect national laws which require that certain ***other*** devices may also only be supplied on a medical prescription. ***Direct to consumer advertising of devices classed as prescription only by this Regulation shall be illegal.***

The following devices may only be supplied on a medical prescription:

- 1) Class D devices;***
- 2) Class C devices in the following categories:***
 - (a) devices for genetic testing;***
 - (b) companion diagnostics.***

By derogation, justified by the attainment of a high level of public health protection, Members States may maintain or introduce national provisions allowing special class D tests to also be available without a medical prescription. In that

case, they shall duly inform the Commission.

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 to decide that other class C tests may only be supplied on a medical prescription after consultation with stakeholders.

Amendment 41

Proposal for a regulation

Article 1 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7a. The regulation of in-vitro diagnostic medical devices at Union level shall not interfere with the freedom of Member States to decide whether to restrict the use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation.

Amendments 42 and 43

Proposal for a regulation

Article 2 – paragraph 1 – point 1

Text proposed by the Commission

Amendment

(1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological process or state,

(1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific **direct or indirect** medical purposes of:

- diagnosis, prevention, monitoring, **prediction, prognosis**, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological process or state,

- control or support of conception,
- disinfection or sterilisation of any of the above-mentioned products,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

- control or support of conception,
- disinfection or sterilisation of any of the above-mentioned products,

– ***providing information concerning direct or indirect impacts on health,***

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Amendment 44

Proposal for a regulation

Article 2 – paragraph 1 – point 2 – indent 2

Text proposed by the Commission

- concerning ***a*** congenital ***abnormality***;

Amendment

- concerning congenital ***physical or mental impairments,***

Amendment 45

Proposal for a regulation

Article 2 – paragraph 1 – point 2 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

In vitro diagnostic medical devices used for DNA-testing shall be subject to this Regulation.

Amendment 46

Proposal for a regulation

Article 2 – paragraph 1 – point 4

Text proposed by the Commission

Amendment

(4) ‘device for self-testing’ means any device intended by the manufacturer to be used by lay persons;

(4) ‘device for self-testing’ means any device intended by the manufacturer to be used by lay persons, ***including testing services offered to lay persons by means of information society services;***

Amendment 47

Proposal for a regulation

Article 2 – paragraph 1 – point 6

Text proposed by the Commission

(6) ‘companion diagnostic’ means a device specifically intended *to select* patients with a previously diagnosed condition or predisposition as *eligible* for a *targeted* therapy;

Amendment

(6) ‘companion diagnostic’ means a device specifically intended *for and essential to the selection of* patients with a previously diagnosed condition or predisposition as *suitable or unsuitable* for a *specific* therapy *with a medicinal product or a range of medicinal products*;

Amendment 48

Proposal for a regulation

Article 2 – paragraph 1 – point 12 a (new)

Text proposed by the Commission

Amendment

(12a) ‘novel device’ means:

- a device which incorporates technology (the analyte, technology or test platform) not previously used in diagnostics, or;*
- an existing device which is being used for a new intended purpose for the first time;*

Amendment 49

Proposal for a regulation

Article 2 – paragraph 1 – point 12 b (new)

Text proposed by the Commission

Amendment

(12b) ‘device for genetic testing’ means an in vitro diagnostic medical device the purpose of which is to identify a genetic characteristic of a person which is inherited or acquired during prenatal development;

Amendment 50

Proposal for a regulation

Article 2 – paragraph 1 – point 15 a (new)

Text proposed by the Commission

Amendment

(15a) 'Information Society service' means any service, normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services;

Amendment 51

Proposal for a regulation

Article 2 – paragraph 1 – point 16 – subparagraph 1

Text proposed by the Commission

Amendment

(16) 'manufacturer' means the natural or legal person ***who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device*** under *his* name or trademark.

(16) 'manufacturer' means the natural or legal person ***with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under that person's own name, regardless of whether those operations are carried out by that person or on that person's behalf by a third party. The obligations of this Regulation to be met by manufacturers also apply to natural or legal persons who assemble, package, process, fully refurbish or label one or more ready-made products and/or assign to them their intended purpose as devices with a view to their being placed on the market under that person's own name or trademark.***

Amendment 52

Proposal for a regulation

Article 2 – paragraph 1 – point 21

Text proposed by the Commission

Amendment

(21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients ***or the promotion of public health;***

(21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients ***and which has the legal capacity to carry out such activities; commercial laboratories which provide diagnostic services shall not be considered to be health institutions;***

Amendment 53

Proposal for a regulation

Article 2 – paragraph 1 – point 25

Text proposed by the Commission

(25) 'conformity assessment body' means a body that performs third-party conformity assessment activities including **calibration**, testing, certification and inspection;

Amendment

(25) 'conformity assessment body' means a body that performs third-party conformity assessment activities including testing, certification and inspection;

Amendment 54

Proposal for a regulation

Article 2 – paragraph 1 – point 28

Text proposed by the Commission

(28) 'clinical evidence' means the **information that supports** the scientific validity and performance for the use of a device as intended by the manufacturer;

Amendment

(28) 'clinical evidence' means the **data, positive and negative, supporting the evaluation of** the scientific validity and performance for the use of a device as intended by the manufacturer;

Amendment 55

Proposal for a regulation

Article 2 – paragraph 1 – point 30

Text proposed by the Commission

(30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of **the** analytical and, where applicable, the clinical performance supporting the intended purpose of the device;

Amendment

(30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of **attainment of technical capabilities**, analytical **performance** and, where applicable, the clinical performance supporting the intended purpose of the device;

Amendment 56

Proposal for a regulation

Article 2 – paragraph 1 – point 35

Text proposed by the Commission

(35) 'performance evaluation' means the assessment and analysis of data to establish or verify **the** analytical and, where

Amendment

(35) 'performance evaluation' means the assessment and analysis of data to establish or verify **that the device performs as**

applicable, the clinical performance of a device;

intended by the manufacturer, including the technical, analytical and, where applicable, the clinical performance of a device;

Amendment 57

Proposal for a regulation

Article 2 – paragraph 1 – point 37 a (new)

Text proposed by the Commission

Amendment

(37a) 'ethics committee' means an independent body in a Member State, consisting of health-care professionals and non-medical members including at least one well-experienced, knowledgeable patient or patient representative. Its responsibility is to protect the rights, safety, physical and mental integrity, dignity and well-being of subjects involved in interventional clinical performance studies and other clinical performance studies involving risk for the subject and to provide public assurance of that protection in full transparency. In cases of such studies involving minors, the ethics committee shall include at least one healthcare professional with paediatric expertise.

Amendment 58

Proposal for a regulation

Article 2 – paragraph 1 – point 43 a (new)

Text proposed by the Commission

Amendment

(43a) 'calibrator' means a measurement standard used in the calibration of a device;

Amendment 59

Proposal for a regulation

Article 2 – paragraph 1 – point 44

Text proposed by the Commission

Amendment

(44) '*calibrators and control materials*' means *any* substance, material or article

(44) '*control material*' means *a* substance, material or article intended by *its*

intended by *the* manufacturer *either to establish measurement relationships or* to verify the performance characteristics of a device *in conjunction with the intended purpose of that device*;

manufacturer *to be used* to verify the performance characteristics of a device;

Amendment 60

Proposal for a regulation

Article 2 – paragraph 1 – point 45

Text proposed by the Commission

(45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation and management of a clinical performance study;

Amendment

(45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation, management, *conduct or financing* of a clinical performance study;

Amendment 61

Proposal for a regulation

Article 2 – paragraph 1 – point 47 – indent 2 – point iii

Text proposed by the Commission

(iii) hospitalisation or *extending the duration of* hospitalisation,

Amendment

(iii) hospitalisation or *prolongation of patient* hospitalisation,

Amendment 62

Proposal for a regulation

Article 2 – paragraph 1 – point 48

Text proposed by the Commission

(48) 'device deficiency' means any inadequacy in the identity, quality, *durability*, reliability, safety or performance of a device for performance evaluation, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;

Amendment

(48) 'device deficiency' means any inadequacy in the identity, quality, *stability*, reliability, safety or performance of a device for performance evaluation, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;

Amendment 63

Proposal for a regulation

Article 2 – paragraph 1 – point 48 a (new)

Text proposed by the Commission

Amendment

(48a) 'inspection' means an official review, carried out by a competent authority, of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by that authority to be related to a clinical performance study and that may be located at the site of the trial, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect;

Amendment 64

Proposal for a regulation

Article 2 – paragraph 1 – point 55

Text proposed by the Commission

Amendment

(55) 'field safety notice' means the communication sent by the manufacturer to users or customers in relation to a field safety corrective action;

(55) 'field safety notice' means the communication sent by the manufacturer to users, ***waste disposal operators*** or customers in relation to a field safety corrective action;

Amendment 65

Proposal for a regulation

Article 2 – paragraph 1 – point 56 a(new)

Text proposed by the Commission

Amendment

(56a) 'unannounced inspection' means an inspection conducted without advance notice;

Amendment 66

Proposal for a regulation

Article 3

Text proposed by the Commission

1. The Commission may, at the request of a Member State *or on its own initiative*, by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of an in vitro diagnostic medical devices or of an accessory to an in vitro diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

2. The Commission shall ensure the sharing of expertise between Member States in the fields of in vitro diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.

Amendment

1. The Commission may *on its own initiative or shall* at the request of a Member State, by means of implementing acts *on the basis of the opinions of the MDCG and the MDAC referred to in Articles 76 and 76a respectively*, determine whether or not a specific product, or category or group of products, *including borderline products*, falls within the definitions of an in vitro diagnostic medical devices or of an accessory to an in vitro diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

Amendment 67

Proposal for a regulation

Chapter II – title

Text proposed by the Commission

Chapter *II*

Making available of devices, obligations of economic operators, CE marking, free movement

Amendment

Chapter *VI**

Making available *and application* of devices, obligations of economic operators, CE marking, free movement

** As a consequence of this amendment, this Chapter will cover Articles 4 to 20.*

Amendment 68

Proposal for a regulation

Article 4 – paragraph 3

Text proposed by the Commission

3. Demonstration of conformity with the general safety and performance requirements shall **be based on** clinical evidence in accordance with Article 47.

Amendment

3. Demonstration of conformity with the general safety and performance requirements shall **include** clinical evidence in accordance with Article 47.

Amendment 69

Proposal for a regulation

Article 4 – paragraph 5 – subparagraph 1

Text proposed by the Commission

With the exception of Article 59(4), the requirements of this Regulation shall not apply to devices classified as class A, B and C, in accordance with the rules set out in Annex VII, and manufactured and used only within a single health institution, provided manufacture and use occur solely under the health institution's single quality management system, and the health institution is **compliant** with standard EN ISO 15189 or any other equivalent recognised standard. Member States **may** require that the health institutions submit to the competent authority a list of such devices which have been manufactured and used on their territory and **may** make the manufacture and use of the devices concerned subject to further safety requirements.

Amendment

With the exception of Article 59(4), the requirements of this Regulation shall not apply to devices classified as class A, B and C, in accordance with the rules set out in Annex VII, and manufactured and used only within a single health institution, provided manufacture and use occur solely under the health institution's single quality management system, and the health institution is **accredited** with standard EN ISO 15189 or any other equivalent recognised standard. **However, the requirements of this Regulation shall continue to apply to clinical or commercial pathology laboratories which do not have health care (i.e. care and treatment of patients) or the promotion of public health as their primary purpose.** Member States **are to** require that the health institutions submit to the competent authority a list of such devices which have been manufactured and used on their territory and **shall** make the manufacture and use of the devices concerned subject to further safety requirements.

Amendment 70

Proposal for a regulation

Article 4 – paragraph 5 – subparagraph 2

Text proposed by the Commission

Devices classified as class D in accordance with the rules set out in Annex VII, *even* if manufactured and used within a single health institution, shall *comply with* the requirements of this Regulation. *However, the provisions regarding CE marking set out in Article 16 and the obligations referred to in Articles 21 to 25 shall not apply to those devices.*

Amendment

Devices classified as class D in accordance with the rules set out in Annex VII, if manufactured and used within a single health institution, shall *be exempt from* the requirements of this Regulation, *with the exception of Article 59(4) and general safety performance requirements set out in Annex I where the following conditions are met:*

(a) the recipient patient or patient group's specific needs cannot be met by an available CE-marked device as such, and therefore, either a CE-marked device needs to be modified or a new device needs to be manufactured;

(b) the health institution is accredited to ISO standard 15189 quality management system, or any other equivalent recognised standard;

(c) the health institution provides the Commission and the competent authority referred to in Article 26 with a list of such devices, which shall include a justification of their manufacturing, modification or use. This list shall be regularly updated.

The Commission shall verify that the devices on that list are eligible for exemption in accordance with the requirements under this paragraph.

The information on exempt devices shall be made public.

Member States shall retain the right to restrict the in-house manufacture and use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation, and may also make the manufacture and use of the devices concerned subject to further safety requirements. In such cases, Member States shall inform the Commission and the other Member States

accordingly.

Amendment 71

Proposal for a regulation

Article 4 – paragraph 6

Text proposed by the Commission

Amendment

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 85, amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer.

deleted

Amendment 271

Proposal for a regulation

Article 4 a (new)

Text proposed by the Commission

Amendment

Article 4a

Genetic information, counselling and informed consent

1. A device may only be used for the purpose of a genetic test if the indication is given by persons admitted to the medical profession under the applicable national legislation after a personal consultation.

2. A device may be used for purposes of a genetic test only in a way that the rights, safety and well-being of the subjects are protected and that the clinical data generated in the course of the genetic testing are going to be reliable and robust.

3. Information. Before using a device for the purpose of a genetic test the person mentioned in paragraph 1 shall provide the person concerned with appropriate information on the nature, the significance and the implications of the

genetic test.

4. Genetic counselling. Appropriate genetic counselling is mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has been diagnosed. It shall include medical, ethical, social, psychological and legal aspects and has to be addressed by physicians or another person qualified under national law in genetic counselling.

The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of his or her family.

5. Consent. A device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The consent has to be given explicitly and in writing. It can be revoked at any time in writing or orally.

6. Testing of minors and incapacitated subjects. In case of minors the informed consent of the parents or legal representative or minors themselves shall be obtained in accordance with national laws; consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor. In case of incapacitated subjects not able to give informed legal consent, the informed consent of the legal representative shall be obtained; consent must represent the presumed will of the incapacitated subject and may be revoked at any time, without detriment to the person.

7. A device may only be used for the determination of sex in connection with prenatal diagnosis, if the determination fulfils a medical purpose and if there is a risk of serious gender specific hereditary diseases. By way of derogation from Article 2(1) and (2) this also applies to products which are not intended to fulfil a

specific medical purpose.

8. The provisions of this Article on the use of devices for the purpose of genetic tests do not prevent the Member States from maintaining or introducing for reasons of health protection or public order more stringent national legislation in this field.

Amendment 73

Proposal for a regulation

Article 5 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Service providers providing means of distance communication shall be obliged, upon receiving a request from the competent authority, to disclose the details of entities engaging in distance selling.

Amendment 74

Proposal for a regulation

Article 5 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. There shall be a prohibition on the marketing, placing in use, distribution, delivery and making available of products whose names, labelling or instructions for use may mislead with regard to the product's characteristics and effects by:

a) ascribing characteristics, functions and effects to the product which the product does not have;

b) creating the false impression that treatment or diagnosis using the product is sure to be successful, or failing to inform of a likely risk associated with the use of the product in line with its intended use or for a longer-than-anticipated period;

c) suggesting uses or characteristics of the product other than those declared when the conformity assessment was carried out.

Promotional materials, presentations and information about the products may not mislead in the manner referred to in the first subparagraph.

Amendment 75

Proposal for a regulation

Article 7 – paragraphs 1 and 1 a (new)

Text proposed by the Commission

1. Where no harmonised standards exist or where **relevant harmonised standards are not sufficient**, the Commission shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evidence and post-market follow-up set out in Annex XII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).

Amendment

1. Where no harmonised standards exist or where **there is a need to address public health concerns**, the Commission, **after having consulted the MDCG and the MDAC**, shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evidence and post-market follow-up set out in Annex XII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).

1a. Before adopting CTS referred to in paragraph 1, the Commission shall ensure that the CTS have been developed with the appropriate support of the relevant stakeholders and that they are coherent with the European and international standardisation system. CTS are coherent if they do not conflict with European standards, meaning they cover areas where no harmonised standards exist, the adoption of new European standards is not envisaged within a reasonable period, where existing standards have not gained market uptake or where those standards have become obsolete or have been demonstrated as clearly insufficient according to vigilance or surveillance data, and where the transposition of the technical specifications into European standardisation deliverables is not envisaged within a reasonable period.

Amendment 76

Proposal for a regulation

Article 8 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.

Amendment

deleted

Amendment 77

Proposal for a regulation

Article 8 – paragraph 6 – subparagraph 1

Text proposed by the Commission

Proportionate to the risk class and the type of device, manufacturers of devices shall institute and keep up to date a systematic procedure to collect and review experience gained from their devices placed on the market or put into service, and to apply any necessary corrective action, hereinafter referred to as ‘post-market surveillance plan’. The post-market surveillance plan shall set out the process for collecting, recording and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market follow-up in accordance with Part B of Annex XII. Where post-market follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan.

Amendment

Proportionate to the risk class and the type of device, manufacturers of devices shall institute and keep up to date a systematic procedure to collect and review experience gained from their devices placed on the market or put into service, and to apply any necessary corrective action, hereinafter referred to as ‘post-market surveillance plan’. The post-market surveillance plan shall set out the process for collecting, recording, ***communicating to the electronic system on vigilance referred in Article 60*** and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market follow-up in accordance with Part B of Annex XII. Where post-market follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan ***and subject to approval by the competent authority.***

Amendments 78, 79 and 263

Proposal for a regulation

Article 8 – paragraph 7

Text proposed by the Commission

7. Manufacturers shall ensure that **the device is accompanied by** the information to be supplied in accordance with Section 17 of Annex I in an official Union language which can be easily understood by the intended user. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user.

For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be provided in the language(s) of the Member State where the device reaches its intended user.

Amendment

7. Manufacturers shall ensure that the information to be supplied **for the device** in accordance with Section 17 of Annex I **is provided** in an official Union language which can be easily understood by the intended user. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user.

For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be **easily understandable and** provided in the **official Union** language(s) of the Member State where the device reaches its intended user.

Amendment 80

Proposal for a regulation

Article 8 – paragraph 8

Text proposed by the Commission

8. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the distributors and, where applicable, the authorised representative accordingly.

Amendment

8. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the **responsible national competent authority, the distributors, importers** and, where applicable, the authorised representative accordingly.

Amendment 81

Proposal for a regulation

Article 8 – paragraph 9 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

If a competent authority considers or has reason to believe that a device has caused damage, it shall ensure, where this is not already provided for by national litigation or judicial proceedings, that the potentially harmed user, the user's successor in title, the user's health insurance company or other third parties affected by the damage caused to the user may request the information referred to in the first subparagraph from the manufacturer or his authorised representative while ensuring due regard for the intellectual property rights.

Amendment 82

Proposal for a regulation

Article 8 – paragraph 9 – subparagraph 1 b (new)

Text proposed by the Commission

Amendment

If facts exist that give reason to assume that an in-vitro medical device has caused damage, the potentially harmed user, his successor in title, his compulsory health insurance or other third parties affected by the damage may also demand the information referred to in sentence 1 from the manufacturer or his authorised representative.

This right to information shall also exist, subject to the conditions set forth in sentence 1, against the competent authorities of the Member States which are responsible for the surveillance of the relevant medical device, as well as against any notified body that issued a certificate pursuant to Article 45 or was otherwise involved in the conformity assessment procedure of the medical device in question.

Amendment 83

Proposal for a regulation

Article 8 – paragraph 10a (new)

Text proposed by the Commission

Amendment

10a. Before placing an in vitro diagnostic medical device on the market, manufacturers shall ensure they are covered by appropriate liability insurance covering the risk of insolvency and any damage to patients or users that can be directly attributed to a manufacturing defect of the same medical device, with a level of coverage proportionate to the potential risk associated with the in vitro diagnostic medical device produced, and in accordance with Directive 85/374/ECC.

Amendment 84

Proposal for a regulation

Article 9 – paragraph 3 – subparagraph 3 – point a

Text proposed by the Commission

Amendment

(a) keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any supplement, issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);

(a) keep ***available the summary of technical documentation (STED) or on request*** the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any supplement, issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);

Amendment 85

Proposal for a regulation

Article 11 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

(b) that an authorised representative in accordance with Article 9 has been designated by the manufacturer;

(b) that ***a manufacturer is identified and, that*** an authorised representative in accordance with Article 9 has been designated by the manufacturer;

Amendment 86

Proposal for a regulation

Article 11 – paragraph 2 – subparagraph 1 – point e

Text proposed by the Commission

(e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use **and EU declaration of conformity**;

Amendment

(e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;

Amendment 87

Proposal for a regulation

Article 11 – paragraph 2 – subparagraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) that the manufacturer has taken out appropriate liability insurance coverage pursuant to Article 8 (10a) , unless the importer himself ensures sufficient coverage that meets the requirements of this provision.

Amendment 88

Proposal for a regulation

Article 11 – paragraph 7

Text proposed by the Commission

Amendment

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative and, if appropriate, **take** the necessary corrective action to bring that device into conformity, withdraw or recall it. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 43 for the device in question, giving details, in particular, of the non-compliance and of any corrective action

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer, **and where applicable** his authorised representative and, if appropriate, **ensure that** the necessary corrective action to bring that device in conformity, withdraw or recall it, **is taken and, implement that action.** Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 43 for the device in question, giving details, in particular, of the non-compliance and of

taken.

any corrective action *they have implemented.*

Amendment 89

Proposal for a regulation Article 12 – paragraph 4

Text proposed by the Commission

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

Amendment

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that, *within the limits of its respective activities*, the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

Amendment 90

Proposal for a regulation Article 13

Text proposed by the Commission

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one *qualified* person who possesses *expert knowledge* in the field of *in vitro* diagnostic medical devices. The *expert knowledge* shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an

Amendment

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one person *responsible for regulatory compliance* who possesses *the requisite expertise* in the field of *in vitro* diagnostic medical devices. The *requisite expertise* shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an

equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, **and at least two years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices;**

(b) **five** years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

2. The **qualified** person shall at least be responsible for ensuring the following matters:

(a) that the conformity of the devices is appropriately assessed before a batch is released;

(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;

(c) that the reporting obligations in accordance with Articles 59 to 64 are fulfilled;

(d) in the case of devices for performance evaluation intended to be used in the context of interventional clinical performance studies or other clinical performance studies involving risks for the subjects, that the statement referred to in Section 4.1 of Annex XIII is issued;

3. The **qualified** person shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

4. Authorised representatives shall have available within their organisation at least one **qualified** person who possesses **expert**

equivalent course of study, in **law**, natural sciences, medicine, pharmacy, engineering or another relevant discipline;

(b) **three** years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

2. The person **responsible for regulatory compliance** shall at least be responsible for ensuring the following matters:

(a) that the conformity of the devices is appropriately assessed before a batch is released;

(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;

(c) that the reporting obligations in accordance with Articles 59 to 64 are fulfilled;

(d) in the case of devices for performance evaluation intended to be used in the context of interventional clinical performance studies or other clinical performance studies involving risks for the subjects, that the statement referred to in Section 4.1 of Annex XIII is issued;

If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1 and 2, their respective areas of responsibility shall be stipulated in writing.

3. The person **responsible for regulatory compliance** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

4. Authorised representatives shall have available within their organisation at least one person **responsible for regulatory**

knowledge regarding the regulatory requirements for *in vitro* diagnostic medical devices in the Union. The **expert knowledge** shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline, **and at least two years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices**;

(b) **five** years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

compliance who possesses **the requisite expertise** regarding the regulatory requirements for *in vitro* diagnostic medical devices in the Union. The **requisite expertise** shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline;

(b) **three** years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

Amendment 91

Proposal for a regulation

Article 14 – paragraph 1 – subparagraph 2

Text proposed by the Commission

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (16) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient.

Amendment

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (16) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient **or a specific limited group of patients within a single healthcare institution.**

Amendment 92

Proposal for a regulation

Article 14 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Distributors or affiliates who carry out, on behalf of the manufacturer, one or more of the activities mentioned under paragraph 2(a) and (b) – are exempted from additional requirements under

paragraphs (3) and (4).

Amendment 264

Proposal for a regulation Article 15 – paragraph 1

Text proposed by the Commission

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be *translated into* the official Union *language or languages required by the Member State(s) in which the device is made available*.

Amendment

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be *issued in one of* the official Union languages.

Amendment 93

Proposal for a regulation Article 15 – paragraph 4

Text proposed by the Commission

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.

Amendment

deleted

Amendment 94

Proposal for a regulation Article 19 – paragraph 1

Text proposed by the Commission

1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device without *significantly* changing its performance or safety characteristics, shall ensure that the article does not adversely

Amendment

1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device without changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety

affect the safety and performance of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States.

and performance of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States.

Amendment 95

Proposal for a regulation Article 19 – paragraph 2

Text proposed by the Commission

2. An article that is intended specifically to replace a part or component of a device and that **significantly** changes the performance or safety characteristics of the device shall be considered a device.

Amendment

2. An article that is intended specifically to replace a part or component of a device and that changes the performance or safety characteristics of the device shall be considered **as a device and shall meet the requirements laid down in this Regulation.**

Amendment 101

Proposal for a regulation Chapter III – title

Text proposed by the Commission

Chapter **III**

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance, European databank on medical devices

Amendment

Chapter **VII***

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance, European databank on medical devices

** As a consequence of this amendment, this Chapter will cover Articles 21 to 25.*

Amendment 96

Proposal for a regulation Article 22 – paragraph 2 – point e – point i

Text proposed by the Commission

(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be **three** years after its designation;

Amendment

(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be **five** years after its designation;

Amendment 97

Proposal for a regulation

Article 22 – paragraph 8 – point b

Text proposed by the Commission

(b) the legitimate interest in protecting commercially sensitive information;

Amendment

(b) the legitimate interest in protecting commercially sensitive information, ***to the extent that it does not undermine public health protection;***

Amendment 98

Proposal for a regulation

Article 22 – paragraph 8 – point e a (new)

Text proposed by the Commission

Amendment

(ea) compatibility with medical device identification systems already on the market.

Amendment 99

Proposal for a regulation

Article 22 – paragraph 8 – point e b (new)

Text proposed by the Commission

Amendment

(eb) compatibility with the other traceability systems used by medical device stakeholders.

Amendment 100

Proposal for a regulation

Article 23 – paragraph 1

Text proposed by the Commission

Amendment

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information that is necessary and proportionate to describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be submitted by the economic operators are laid down in

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information that is necessary and proportionate to describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer, ***and to ensure transparency and safe and effective use by making available to users***

current evidence concerning the clinical validity and, where applicable, utility of the device. The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.

Amendment 102

Proposal for a regulation Article 24

Text proposed by the Commission

Summary of safety and performance

1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up *a summary of safety and performance. It shall be written in a way that is clear to the intended user.* The draft *of this summary* shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with *Article 40 and shall be validated by that body.*

2. The Commission may, by means of implementing acts, set out *the form and the presentation of the data elements to be included in the summary of safety and performance.* Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).

Amendment

Safety and clinical performance report

1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up *a report on the safety and clinical performance of the device based on the full information collected during the clinical performance study. The manufacturer shall also draw up a summary of that report which shall be written in a way that is easy for a lay person to understand in the official language(s) of the country where the device is made available on the market.* The draft *report* shall be part of the documentation to be submitted to *and validated by* the notified body, *and where relevant by the special notified body,* involved in the conformity assessment in accordance with *Articles 40 and 43a.*

1a. The summary referred to in paragraph 1 shall be made available to the public through a Eudamed in accordance with provisions under point (b) of Article 25(2)(b) and point 15 of Annex V, Part A.

2. The Commission may, by means of implementing acts, set out *the format of the presentation of the data elements to be included in both the report and the summary referred to in paragraph 1.* Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).

Amendment 103

Proposal for a regulation

Article 25 – paragraph 2 – points f a and f b (new)

Text proposed by the Commission

Amendment

(fa) the electronic system on registration of subsidiaries and subcontracting referred to in Article 28a.

(fb) the electronic system on "Special notified bodies" referred to in Article 41b.

Amendment 104

Proposal for a regulation

Article 26 - paragraph 5

Text proposed by the Commission

Amendment

5. The national authority responsible for notified bodies shall safeguard the **confidentiality** of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.

5. The national authority responsible for notified bodies shall safeguard the **confidential aspects** of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.

Amendment 105

Proposal for a regulation

Article 26 – paragraph 6

Text proposed by the Commission

Amendment

6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel **at its disposal** for the proper performance of its tasks.

6. The national authority responsible for notified bodies shall have a sufficient number of **permanent and** competent personnel **"in house"**, for the proper performance of its tasks. **Compliance with that requirement shall be assessed in the peer-review referred to in paragraph 8.**

In particular, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out product related reviews shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.5. of Annex VI.

Similarly, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out audits of the manufacturer's quality management system shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.6. of Annex VI.

Without prejudice to Article 31(3), where a national authority is responsible for the designation of notified bodies in the field of products other than in vitro diagnostic medical devices, the competent authority for in vitro diagnostic medical devices shall be consulted on all aspects specifically related to such devices.

Where a national authority is responsible for the designation of notified bodies in the field of products other than in vitro diagnostic medical devices, the competent authority for in vitro diagnostic medical devices shall be consulted on all aspects specifically related to such devices.

Amendment 106

Proposal for a regulation Article 26 – paragraph 7

Text proposed by the Commission

7. Member States shall provide the Commission and the other Member States with information on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto.

Amendment

*7. The ultimate responsibility for the notified bodies and the national authority responsible for notified bodies lies with the Member State in which they are located. The Member State is required to check that the designated national authority responsible for notified bodies performs its work on the assessment, designation and notification of conformity assessment bodies and for the monitoring of the notified bodies properly and that the designated national authority responsible for notified bodies works impartially and objectively. Member States shall provide the Commission and the other Member States with **all** information **they request** on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto. **Such information shall be publicly available subject to Article 80.***

Amendment 107

Proposal for a regulation

Article 26 - paragraph 8

Text proposed by the Commission

8. The national authority responsible for notified bodies shall be peer-reviewed every second year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review.

The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission *may* participate in the review. The outcome of the peer-review shall be communicated to all Member States *and to the Commission* and a summary of the outcome shall be made publicly available.

Amendment

8. The national authority responsible for notified bodies shall be peer-reviewed every second year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review.

The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission *shall* participate in the review. The outcome of the peer-review shall be communicated to all Member States and a summary of the outcome shall be made publicly available.

Amendment 108

Proposal for a regulation

Article 27 - paragraph 1

Text proposed by the Commission

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. Minimum requirements to be met by notified bodies are set out in Annex VI.

Amendment

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. *In this respect, permanent "in house" administrative, technical and scientific personnel, with medical, technical and, where needed, pharmacological knowledge shall be ensured. Permanent "in house" personnel shall be used, but notified bodies may hire external experts on an ad hoc and temporary basis as and when*

needed. Minimum requirements to be met by notified bodies are set out in Annex VI. In particular, in accordance with point 1.2. of Annex VI, the notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities and avoid conflict of interests.

The notified body shall publish a list of its staff responsible for the conformity assessment and certification of medical devices. This list shall at least contain the qualifications, CV and declaration of interests for each member of staff. The list shall be sent to the national authority responsible for notified bodies which shall check that the staff satisfy the requirements of this Regulation. The list shall also be sent to the Commission.

Amendment 109

Proposal for a regulation Article 28

Text proposed by the Commission

Amendment

-1. Notified bodies shall have permanent "in house" competent personnel and expertise, both in technical fields linked with the assessment of the performance of the devices, and in the medical field. They shall have the capacity to evaluate "in house" the quality of subcontractors.

Contracts may be awarded to external experts for the assessment of in vitro diagnostic medical devices or technologies in particular where clinical expertise is limited.

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.
2. Notified bodies shall take full

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.
2. Notified bodies shall take full

responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the agreement of the legal or natural person that applied for conformity assessment.

4. Notified bodies shall **keep at the disposal of** the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

2a. Notified bodies shall make publicly available the list of subcontractors or subsidiaries, the specific tasks for which they are responsible and the declarations of interest of their personnel.

3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the **explicit** agreement of the legal or natural person that applied for conformity assessment.

4. **At least once a year**, notified bodies shall **submit to** the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

4a. The annual assessment of notified bodies as provided for in Article 33(3) shall include verification of the compliance of the subcontractor(s) or the subsidiary/ies of notified bodies with the requirements set out in Annex VI.

Amendment 110

Proposal for a regulation Article 28 a (new)

Text proposed by the Commission

Amendment

Article 28 a

Electronic system on registration of subsidiaries and subcontractors

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on subcontractors and subsidiaries, as well as on the specific tasks for which they are responsible.

2. Before subcontracting can effectively take place, the notified body which

intends to subcontract specific tasks connected with conformity assessment or have recourse to a subsidiary for specific tasks connected with conformity assessment, shall register their name(s) together with their specific tasks.

3. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.

4. The data contained in the electronic system shall be accessible to the public.

Amendment 111

Proposal for a regulation Article 29 – paragraph 1

Text proposed by the Commission

1. A conformity assessment body shall submit an application for notification to the national authority responsible for notified bodies of the Member State in which it is established.

Amendment

1. A conformity assessment body shall submit an application for notification to the national authority responsible for notified bodies of the Member State in which it is established.

In case a conformity assessment body wants to be notified for devices referred to in Article 41a(1), it shall indicate so and submit an application for notification to the EMA in accordance with Article 41a

Amendment 112

Proposal for a regulation Article 30 – paragraph 3

Text proposed by the Commission

3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of at least **two** experts chosen from a list of experts who are qualified in the assessment of conformity assessment bodies. The list shall be drawn up by the Commission in cooperation with the MDCG. At least one of these experts shall be a representative of the Commission **who**

Amendment

3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of at least **three** experts chosen from a list of experts who are qualified in the assessment of conformity assessment bodies **and free of conflicts of interest with the applicant conformity assessment body**. The list shall be drawn up by the

shall lead the joint assessment team.

Commission in cooperation with the MDCG. At least one of these experts shall be a representative of the Commission, **and at least one other shall come from a Member State other than the one in which the applicant conformity assessment body is established. The Commission representative** shall lead the joint assessment team. **In case the conformity assessment body has asked to be notified for devices referred to in Article 41 a(1), EMA shall also be part of the joint assessment team.**

Amendment 113

Proposal for a regulation Article 30 – paragraph 4

Text proposed by the Commission

4. Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 29 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 29(2), unless the Commission representative mentioned in Article 30(3) requests the on-site assessment.

Findings regarding non-compliance of a body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team **with a view to finding common agreement with respect to the assessment of the application. Divergent opinions shall be identified in** the assessment report

Amendment

4. Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 29 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 29(2), unless the Commission representative mentioned in Article 30(3) requests the on-site assessment.

Findings regarding non-compliance of **an applicant conformity assessment** body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team. **The national authority shall set out in the assessment report the measures that the notified body shall take to ensure**

of the national authority responsible.

compliance of that applicant conformity assessment body with the requirements set out in Annex VI. In the event of a disagreement, a separate opinion drawn up by the assessment team setting out its reservations regarding notification shall be appended to the assessment report of the national authority responsible.

Amendment 114

Proposal for a regulation Article 30 – paragraph 5

Text proposed by the Commission

5. The national authority responsible for notified bodies shall submit its assessment report and its draft notification to the Commission which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.

Amendment

5. The national authority responsible for notified bodies shall submit its assessment report and its draft notification to the Commission which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. *If the assessment team draws up a separate opinion, that too shall be submitted to the Commission for forwarding to the MDCG.* Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.

Amendment 115

Proposal for a regulation Article 30 – paragraph 6

Text proposed by the Commission

6. The joint assessment team shall provide its opinion regarding the assessment report **and** the draft notification within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification *which the* relevant national authority shall **duly take into consideration for** its decision on the designation of the notified body.

Amendment

6. The joint assessment team shall provide its **final** opinion regarding the assessment report, the draft notification **and, where appropriate, the separate opinion drawn up by the assessment team,** within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification. **The** relevant national authority shall **base** its decision on the

designation of the notified body *on the recommendation by the MDCG. Where its decision differs from the MDCG recommendation, the relevant national authority shall provide the MDCG in writing all the necessary justifications for its decision.*

Amendment 116

Proposal for a regulation Article 31 – paragraph 2

Text proposed by the Commission

2. Member States *may* notify only conformity assessment bodies which satisfy the requirements set out in Annex VI.

Amendment

2. Member States *shall* notify only conformity assessment bodies which satisfy the requirements set out in Annex VI *and for which the application assessment procedure has been completed in accordance with Article 30.*

Amendment 117

Proposal for a regulation Article 31 – paragraph 3

Text proposed by the Commission

3. *Where a national authority responsible for notified bodies is responsible for designation of notified bodies in the field of products other than in vitro diagnostic medical devices, the competent authority for in vitro diagnostic medical devices shall provide, prior to the notification, a positive opinion on the notification and its scope.*

Amendment

deleted

Amendment 118

Proposal for a regulation Article 31 – paragraph 4 – subparagraph 1

Text proposed by the Commission

4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures and the

Amendment

4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures, the *risk*

type of devices which the notified body is authorised to assess.

class and the type of devices which the notified body is authorised to assess.

Amendment 119

Proposal for a regulation Article 31 – paragraph 8

Text proposed by the Commission

8. When a Member State or the Commission raises objections in accordance with paragraph 7, the effect of the notification shall be suspended. In this case, the Commission shall bring the matter before the MDCG within 15 days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 28 days after the matter has been brought before it. If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.

Amendment

8. When a Member State or the Commission raises objections in accordance with paragraph 7, the effect of the notification shall be ***immediately*** suspended. In this case, the Commission shall bring the matter before the MDCG within 15 days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 28 days after the matter has been brought before it. If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.

Amendment 120

Proposal for a regulation Article 31 – paragraph 9

Text proposed by the Commission

9. Where no objection is raised in accordance with paragraph 7 or where the MDCG or the Commission, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted fully ***or partially***, the Commission shall publish the notification accordingly.

Amendment

9. Where no objection is raised in accordance with paragraph 7 or where the MDCG or the Commission, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted fully, the Commission shall publish the notification accordingly.

The Commission shall also enter information on the notification of the notified body into the electronic system referred to in the second subparagraph of Article 25. That information shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and

the recommendation of the MDCG, as referred to in this article.

The full details of the notification, including the class and the typology of devices, as well as the annexes, shall be made publicly available.

Amendment 121

Proposal for a regulation Article 32 – paragraph 2

Text proposed by the Commission

2. The Commission shall make accessible to the public the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified. The Commission shall ensure that the list is kept up to date.

Amendment

2. The Commission shall make *easily* accessible to the public the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified ***and all documents for the notification procedure as referred to in Article 31(5).*** The Commission shall ensure that the list is kept up to date.

Amendment 122

Proposal for a regulation Article 33

Text proposed by the Commission

1. The national authority responsible for notified bodies shall continuously monitor the notified bodies to ensure ongoing compliance with the requirements set out in Annex VI. The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority to verify compliance with those criteria.

Notified bodies shall, without delay, inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity

Amendment

1. The national authority responsible for notified bodies, ***and where applicable EMA,*** shall continuously monitor the notified bodies to ensure ongoing compliance with the requirements set out in Annex VI. The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority to verify compliance with those criteria.

Notified bodies shall, without delay, ***and within 15 days at the latest,*** inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct

assessment procedures relating to the devices for which they have been designated.

2. Notified bodies shall respond without delay to requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission **unless** there is a legitimate reason for not doing so **in which case both sides may consult the MDCG. The notified body or their national authority responsible for notified bodies may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated confidential.**

3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body under its responsibility still satisfies the requirements set out in Annex VI. This assessment shall include an on-site visit to each notified body.

4. **Three** years after notification of a notified body, and again every **third** year thereafter, the assessment to determine whether the notified body still **satisfies** the requirements set out in Annex VI shall be

the conformity assessment procedures relating to the devices for which they have been designated.

2. Notified bodies shall respond without delay, **and within 15 days at the latest**, to requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission. **Where** there is a legitimate reason for not doing so, **the notified bodies shall explain these reasons in writing and shall consult the MDCG, which shall then issue a recommendation. The national authority responsible for notified bodies shall comply with the MDCG's recommendation.**

3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body under its responsibility still satisfies the requirements set out in Annex VI, **including an assessment of whether its subcontractor(s) and subsidiary/-ies satisfy those requirements.** This assessment shall include an **unannounced inspection through an** on-site visit to each notified body, **and to each subsidiary or subcontractor within or outside the Union, if relevant.**

The assessment shall also include a review of samples of the design dossier assessments carried out by the notified body to determine the ongoing competence of the notified body and quality of its assessments, in particular the notified body's ability to evaluate and assess clinical evidence.

4. **Two** years after notification of a notified body, and again every **second** year thereafter, the assessment to determine whether the notified body **and its subsidiaries and subcontractors** still

conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 30(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body with the requirements set out in Annex VI.

5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities. This report shall contain a summary which shall be made publicly available.

satisfy the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 30(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body, *or a subsidiary or subcontractor of a notified body*, with the requirements set out in Annex VI.

For special notified bodies under Article 41a, the assessment referred to in this paragraph shall be performed every year.

The comprehensive results of the assessments shall be published.

5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities. This report shall contain a summary which shall be made publicly available.

5a. Every year, the notified bodies shall forward an annual activity report setting out the information referred to in Annex VI, point 5 to the competent authority and to the Commission, which shall forward it to the MDCG.

Amendment 123

Proposal for a regulation Article 34 – paragraph 2

Text proposed by the Commission

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure

Amendment

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure

to meet those requirements or fulfil those obligations. *A suspension shall not exceed a period of one year, renewable once for the same period.* Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

The national authority responsible for notified bodies shall immediately inform the Commission *and* the other Member States of any suspension, restriction or withdrawal of a notification.

to meet those requirements or fulfil those obligations. *Suspension shall apply until a decision to annul the suspension has been reached by the MDCG, which shall follow an assessment by a joint assessment team designated in accordance with the procedure described in Article 30(3).*

Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

The national authority responsible for notified bodies shall immediately *and within 10 days at the latest*, inform the Commission, the other Member States *and the relevant manufacturers and health professionals* of any suspension, restriction or withdrawal of a notification.

Amendment 124

Proposal for a regulation Article 34 – paragraph 3

Text proposed by the Commission

3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are either processed by another notified body or kept available for the national authorities responsible for notified bodies and for market surveillance at their request.

Amendment

3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall *inform the Commission and shall* take appropriate steps to ensure that the files of the notified body concerned are either processed by another notified body or kept available for the national authorities responsible for notified bodies and for market surveillance at their request.

Amendment 125

Proposal for a regulation Article 34 – paragraph 4

Text proposed by the Commission

4. The national authority responsible for notified bodies shall assess whether the reasons which gave rise to the *change to* the notification have an impact on the certificates issued by the notified body and, within three months after having notified

Amendment

4. The national authority responsible for notified bodies shall assess whether the reasons which gave rise to the *suspension, restriction or withdrawal of* the notification have an impact on the certificates issued by the notified body and,

the changes to the notification, shall submit a report on its findings to the Commission and the other Member States. Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.

within three months after having notified the changes to the notification, shall submit a report on its findings to the Commission and the other Member States. Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, **and at the latest 30 days after the publication of the report**, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.

With a view to verifying whether the reasons for the suspension, restriction or withdrawal of the notification have implications for the certificates issued, the national authority responsible shall ask the relevant manufacturers to supply evidence of conformity at notification, and the manufacturers shall have 30 days in which to respond to that request.

Amendment 126

Proposal for a regulation Article 34 – paragraph 5

Text proposed by the Commission

5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:

(a) in the case of suspension of a notification: on condition that, within three months of the suspension, ***either the competent authority for in vitro diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or another notified body responsible for in vitro diagnostic medical devices confirms***

Amendment

5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:

(a) in the case of suspension of a notification: on condition that, within three months of the suspension another notified body responsible for in vitro diagnostic medical devices confirms in writing that it is assuming the functions of the notified body during the period of suspension;

in writing that it is assuming the functions of the notified body during the period of suspension;

(b) in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.

The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.

(b) in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.

The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately ***and within 10 days at the latest***, inform the Commission, the other Member States and the other notified bodies thereof.

The Commission shall immediately and within 10 days at the latest enter information on the changes to the notification of the notified body into the electronic system referred to in the second subparagraph of Article 25.

Amendment 127

Proposal for a regulation Article 35 – paragraph 1

Text proposed by the Commission

1. The Commission shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body of the requirements set out in Annex VI or the obligations to which it is subject. It may also commence such investigations on its own initiative.

Amendment

1. The Commission shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body of the requirements set out in Annex VI or the obligations to which it is subject. It may also commence such investigations on its own initiative, ***including the unannounced inspection of the notified body by a joint assessment team whose composition meets the conditions set out in Article 30(3).***

Amendment 128

Proposal for a regulation

Article 35 – paragraph 3 – subparagraph 1

Text proposed by the Commission

3. Where the Commission *ascertains* that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification if necessary.

Amendment

3. Where the Commission, *in consultation with the MDCG, decides* that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification, if necessary, *in line with Article 34(2)*.

Amendment 129

Proposal for a regulation

Article 37 – paragraph 1

Text proposed by the Commission

The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies referred to in Article 39 of Regulation [Ref. of future Regulation on medical devices].

Amendment

The Commission, *in consultation with the MDCG*, shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies referred to in Article 39 of Regulation [Ref. of future Regulation on medical devices]. *This group shall meet on a regular basis and at least twice a year.*

Amendment 130

Proposal for a regulation

Article 37 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

The Commission or the MDCG may request the participation of any notified body.

Amendment 131

Proposal for a regulation

Article 37 – paragraph 2 b (new)

The Commission may, by means of implementing acts, adopt measures setting out the modalities for the functioning of the coordination group of notified bodies as set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

Amendment 132

Proposal for a regulation

Article 38

Text proposed by the Commission

Amendment

Fees

Fees for the activities of national authorities

1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation **and** cost-effectiveness. Particular attention shall be paid to the interests of notified bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 29(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.

1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation, cost-effectiveness **and the need to create a level-playing field across Member States**. Particular attention shall be paid to the interests of notified bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 29(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.

These fees shall be proportionate and consistent with national standards of living. The level of fees shall be made

public.

Amendment 133

Proposal for a regulation Article 38 a (new)

Text proposed by the Commission

Amendment

Article 38a

Transparency on fees charged by notified bodies for conformity assessment activities

- 1. Member States shall adopt provisions on standard fees for notified bodies.***
- 2. Fees shall be comparable across Member States. The Commission shall provide guidelines to facilitate comparability of those fees within 24 months of the date of entry into force of this Regulation.***
- 3. Member States shall transmit their list of standard fees to the Commission.***
- 4. The national authority shall ensure that the notified bodies make the lists of standard fees for the conformity assessment activities publicly available.***

Amendment 134

Proposal for a regulation Chapter V – title

Text proposed by the Commission

Amendment

Chapter V

Chapter III*

***Classification and conformity* assessment**

***Conformity* assessment**

** As a consequence of this amendment, this Chapter will cover Articles 40, 41, **41a**, **41b**, **41c**, **42a**, 43, 44, 45, 46.*

Amendment 135

Proposal for a regulation Chapter V – section 1 – title

Text proposed by the Commission

Section 1 – Classification

Amendment

Chapter II*

**Classification of *in vitro* diagnostic
medical devices**

** As a consequence of this amendment, this
Chapter will cover Article 39.*

Amendment 136

Proposal for a regulation

Article 39 – paragraph 1

Text proposed by the Commission

1. Devices shall be divided into class A, B, C and D, taking into account their intended purpose and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.

Amendment

1. Devices shall be divided into class A, B, C and D, taking into account their intended purpose, **novelty, complexity** and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.

Amendment 137

Proposal for a regulation

Article 39 – paragraph 2 – subparagraph 2

Text proposed by the Commission

At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision.

Amendment

At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision. ***That decision shall be made publically available in the European databank.***

Amendment 138

Proposal for a regulation

Article 39 – paragraph 3 – subparagraph 1

Text proposed by the Commission

The Commission may, at the request of a Member State, ***on its own initiative***, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view

Amendment

The Commission may ***on its own initiative or shall*** at the request of a Member State, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view

to determining their classification.

to determining their classification. *Such a decision shall in particular be taken in order to resolve divergent decisions as regards the classification of devices between Member States.*

Amendment 139

Proposal for a regulation

Article 39 – paragraph 4 – introductory part

Text proposed by the Commission

4. In the light of technical progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 as regards the following:

Amendment

4. In the light of technical progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission, **having consulted relevant stakeholders, including healthcare professionals' organisations, and manufacturers' associations**, shall be empowered to adopt delegated acts in accordance with Article 85 as regards the following:

Amendment 140

Proposal for a regulation

Article 40 – paragraph 2 – subparagraph 2

Text proposed by the Commission

In addition, where a reference laboratory is designated in accordance with Article 78, the notified body performing the conformity assessment shall request that reference laboratory to verify compliance of the device with the applicable CTS, **when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX.**

Amendment

In addition, where a reference laboratory is designated in accordance with Article 78, the notified body performing the conformity assessment shall request that reference laboratory to verify **by laboratory testing** compliance of the device with the applicable CTS, **as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX. Laboratory tests performed by a reference laboratory shall focus on in particular analytic sensitivity and specificity using reference materials and diagnostic sensitivity and specificity using specimens from early and established infection.**

Amendment 141

Proposal for a regulation

Article 40 – paragraph 4 – subparagraph 2

Text proposed by the Commission

In addition, for devices for self-testing **and near-patient testing**, the manufacturer shall fulfil the supplementary requirements set out in Section 6.1 of Annex VIII.

Amendment

In addition, for devices for self-testing the manufacturer shall fulfil the supplementary requirements set out in Section 6.1 of Annex VIII.

Amendment 142

Proposal for a regulation

Article 40 – paragraph 5 – subparagraph 2 – point a

Text proposed by the Commission

(a) in the case of devices for near-patient testing, to the requirements set out in Section 6.1 of Annex VIII,

Amendment

deleted

Amendment 143

Proposal for a regulation

Article 40 – paragraph 5 – subparagraph 2 – point c

Text proposed by the Commission

(c) in the case of devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with the metrological requirements.

Amendment

deleted

Amendment 144

Proposal for a regulation

Article 40 – paragraph 10

Text proposed by the Commission

10. In the light of technical progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 26 to 38, or of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission shall be empowered to adopt delegated acts in

Amendment

deleted

accordance with Article 85 amending or supplementing the conformity assessment procedures set out in Annexes VIII to X.

Amendment 145

Proposal for a regulation

Article 41 – paragraph 1

Text proposed by the Commission

Involvement of notified bodies

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. An application may not be lodged in parallel with more than one notified body for the same conformity assessment activity.

Amendment

Involvement of notified bodies *in conformity assessment procedures*

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer *of devices other than those listed in Article 41a(1)*, may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. *Where a manufacturer applies to a notified body located in a Member State other than the one where it is registered, the manufacturer shall inform its national authority responsible for the notified bodies of the application.* An application may not be lodged in parallel with more than one notified body for the same conformity assessment activity.

Amendment 146

Proposal for a regulation

Section 2 a (new) – Title – below Article 41

Text proposed by the Commission

Amendment

Section 2a - Additional provisions for the conformity assessment of high-risk devices: Involvement of special notified bodies

Amendment 147

Proposal for a regulation Article 41 a (new)

Text proposed by the Commission

Amendment

Article 41a

Involvement of special notified bodies in conformity assessment procedures of high-risk devices

- 1. Only special notified bodies (SNB) shall be entitled to conduct conformity assessments for class D devices.***
- 2. Applicant special notified bodies which consider they fulfil the requirements for special notified bodies referred to in Annex VI, point 3.6, shall submit their application to the EMA.***
- 3. The application shall be accompanied by the fee payable to the EMA to cover the costs relating to the examination of the application.***
- 4. The EMA shall select the special notified bodies among applicants, in accordance with requirements listed in Annex VI, and adopt its opinion on the authorisation to perform conformity assessments for devices listed in paragraph 1 within 90 days and send it to the Commission.***
- 5. The Commission shall then publish the notification accordingly and the names of the special notified bodies.***
- 6. This notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the special notified body.
This notification shall be valid for five years and subject to renewal every five years, following a new application to the EMA.***
- 7. The manufacturer of devices specified in paragraph 1 may apply to a special notified body of its choice, whose name***

appears in the electronic system of Article 41b.

8. An application may not be lodged in parallel with more than one special notified body for the same conformity assessment activity.

9. The Special notified body shall notify the EMA and the Commission of applications for conformity assessments for devices specified in paragraph 1.

10. Article 41(2), (3) and (4) apply to special notified bodies.

Amendment 148

Proposal for a regulation Article 41 b (new)

Text proposed by the Commission

Amendment

Article 41b

Electronic system on special notified bodies

1. The Commission, in collaboration with the Agency, shall establish and regularly update an electronic registration system for:

- the registration of applications and granted authorisations to perform conformity assessments as special notified bodies under this Section and to collate and process information on the name of the special notified bodies;

- the exchange of information with national authorities;

-and for the publication of assessment reports.

2. The information collated and processed in the electronic system which relates to special notified bodies shall be entered into the electronic registration system by the EMA.

3. The information collated and processed in the electronic system and which relates to special notified bodies shall be accessible to the public.

Amendment 149

Proposal for a regulation

Article 41 c (new)

Text proposed by the Commission

Amendment

Article 41c

Network of special notified bodies

1. The EMA shall establish, host, coordinate and manage the network of special notified bodies.

2. The network shall have the following objectives:

(a) to help realise the potential of European cooperation regarding highly specialised medical technologies in the area of in vitro diagnostic medical devices;

(b) to contribute to the pooling of knowledge regarding in vitro diagnostic medical devices;

(c) to encourage the development of conformity assessment benchmarks and to help develop and spread best practice within and outside the network;

(d) to help identify the experts in innovative fields;

(e) to develop and update rules on conflicts of interest;and

(f) to find common answers to similar challenges concerning the conduct of conformity assessment procedures in innovative technologies.

3. Meetings of the network shall be convened whenever requested by at least two of its members or by the EMA. It shall meet at least twice a year.

Amendment 150

Proposal for a regulation

Article 42

Text proposed by the Commission

Amendment

Article 42

deleted

Mechanism for scrutiny of certain conformity assessments

Measures pursuant to this paragraph may be justified only by one or more of the following criteria:

- 1. Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class D, with the exception of applications to supplement or renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and performance referred to in Article 24. In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.*
- 2. Within 28 days of receipt of the information referred to in paragraph 1, the MDCG may request the notified body to submit a summary of the preliminary conformity assessment prior to issuing a certificate. Upon suggestion by any of its members or by the Commission, the MDCG shall decide on making such request in accordance with the procedure set out in Article 78(4) of Regulation [Ref. of future Regulation on medical devices]. In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file for submission of a summary of the preliminary conformity assessment. When selecting a specific file for submission, the principle of equal treatment shall be duly taken into account.*

Within 5 days after receipt of the request by the MDCG, the notified body shall inform the manufacturer thereof.

3. The MDCG may submit comments on the summary of the preliminary conformity assessment at the latest 60 days after submission of this summary. Within that period and at the latest 30 days after submission, the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this subparagraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. The notified body shall give due consideration to any comments received in accordance with paragraph 3. It shall convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question. The Commission shall immediately transmit this information to the MDCG.

5. Where deemed necessary for the protection of patient safety and public health, the Commission may determine, by means of implementing acts, specific categories or groups of devices, other than devices classified as class D, to which paragraphs 1 to 4 shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

Measures pursuant to this paragraph may be justified only by one or more of the

following criteria:

(a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;

(b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;

(c) an increased rate of serious incidents reported in accordance with Article 59 in respect of a specific category or group of devices;

(d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices;

(e) public health concerns regarding a specific category or group of devices or the technology on which they are based.

6. The Commission shall make a summary of the comments submitted in accordance with paragraph 3 and the outcome of the conformity assessment procedure accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.

7. The Commission shall set up the technical infrastructure for the data-exchange by an electronic means between notified bodies and MDCG for the purposes of this Article.

8. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the summary of the preliminary conformity assessment in accordance with paragraphs 2 and 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

Amendment 151

Proposal for a regulation Article 42 a (new)

Text proposed by the Commission

Amendment

Article 42a

Case-by-case assessment procedure for the conformity assessments of certain high-risk devices

1. Special notified bodies shall notify the Commission of applications for conformity assessments for Class D devices, with the exception of applications to renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Coordination Group (CG) of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76a. The CG shall immediately transmit the notification and the accompanying documents to the relevant sub-groups.

2. Within 20 days of receipt of the information referred to in paragraph 1, the CG may decide, upon suggestion by at least three of the members of the relevant sub-groups of the ACMD or by the Commission, to request the special notified body to submit the following documents prior to issuing a certificate:

- the summary of the preliminary conformity assessment;***
- the clinical evidence report and the clinical performance study report as referred to in Annex XII;***
- data obtained from the post-market follow-up referred to in Annex XII; and***

- any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation conducted by competent authorities in those countries,

The members of the relevant sub-groups of the ACMD shall decide on making such case-by-case requests notably on the basis of the following criteria:

(a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;

(b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;

(c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;

(d) significant discrepancies in the conformity assessments carried out by different Special notified bodies on substantially similar devices.

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing these criteria.

In its request the ACMD shall indicate the scientifically valid health reason for having selected the specific file.

In the absence of request from the ACMD within 20 days of receipt of the information referred to in paragraph 1, the special notified body shall proceed with the conformity assessment procedure.

3. The ACMD, following the consultation of the relevant sub-groups, shall issue an opinion on the documents referred to in paragraph 2 at the latest 60 days after its submission. Within that period and at the

latest 30 days after submission, the ACMD may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the special notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the ACMD shall not suspend the period for the submission of comments.

4. In its opinion the ACMD may recommend modifications of the documents referred to in paragraph 2.

5. The ACMD shall inform the Commission, the special notified body and the manufacturer of its opinion within 5 days of its adoption.

6. Within 15 days after receipt of the opinion referred to in paragraph 5, the special notified body shall indicate whether or not it agrees with the opinion of the ACMD. In the latter case, it may give written notice to the ACMD that it wishes to request a re-examination of the opinion. In that case, the special notified body shall forward to the ACMD the detailed grounds for the request within 30 days after receipt of the opinion. The ACMD shall immediately transmit this information to the Commission

Within 30 days following receipt of the grounds for the request, the ACMD shall re-examine its opinion. The reasons for the conclusion reached shall be annexed to the final opinion.

7. Within 15 days after its adoption, the ACMD shall send its final opinion to the Commission, the special notified body and the manufacturer.

8. Within 15 days after receipt of the opinion referred to in paragraph 6 in case

of agreement by the special notified body or of the final opinion as referred to in paragraph 7, the Commission shall prepare, on the basis of the opinion, a draft of the decision to be taken in respect of the examined application for conformity assessment. This draft decision shall include or make reference to the opinion referred to in paragraph 6 and 7 as applicable. Where the draft decision is not in accordance with the ACMD opinion, the Commission shall annex a detailed explanation of the reasons for the differences.

The draft decision shall be forwarded to the Member States, the special notified body and the manufacturer.

The Commission shall take a final decision in accordance with and within 15 days after the end of, the examination procedure referred to in Article 84(3).

9. Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to determine, specific categories or groups of devices, other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply during a predefined period of time.

Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.

10. The Commission shall make a summary of the opinions referred to in paragraphs 6 and 7 accessible to the public. It shall not disclose any personal data or information of a commercially confidential nature.

11. The Commission shall set up the technical infrastructure for the data-exchange by electronic means between special notified bodies and the ACMD and between the ACMD and itself for the purposes of this Article.

12. The Commission, by means of implementing acts, may adopt the

modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

13. Special notified bodies shall notify the Commission of applications for conformity assessments for Class D devices, with the exception of applications to renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Coordination Group (CG) of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76a. The CG shall immediately transmit the notification and the accompanying documents to the relevant sub-groups.

Amendment 152

Proposal for a regulation

Article 44 – paragraph 1 – introductory part

Text proposed by the Commission

1. *In cases* where a manufacturer **terminates** his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the outgoing notified body and the incoming notified body. This agreement shall address at least the following aspects:

Amendment

1. Where a manufacturer **decides to terminate** his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, **it shall inform its national authority responsible for the notified bodies of this change.** The modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the outgoing notified body and the incoming notified body. This agreement shall address at least the following aspects:

Amendments 259 and 269

Proposal for a regulation Article 44a (new)

Text proposed by the Commission

Amendment

Article 44a

Additional assessment procedure in extraordinary cases

1. Special notified bodies shall notify the Commission of applications for conformity assessments for Class D devices, where no CTS standard exists, with the exception of applications to renew or supplement existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the Special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Medical Device Coordination Group (MDCG) for an opinion. In making its opinion, the MDCG may seek a clinical assessment from the relevant experts of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76a.

2. Within 20 days of receipt of the information referred to in paragraph 1, the MDCG may decide to request the special notified body to submit the following documents prior to issuing a certificate:

- the clinical evidence report and the clinical performance study report as referred to in Annex XII,***
- data obtained from the post market***

follow-up referred to in Annex XII, and

- *any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation conducted by competent authorities in those countries,*

The members of the MDCG shall decide on making such a request on the basis of the following criteria:

- (a) the novelty of the device with possible major clinical or health impact*
- (b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;*
- (c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;*

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing these criteria.

In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file.

In the absence of a request from the MDCG within 20 days of receipt of the information referred to in paragraph 1, the Special notified body shall proceed with the conformity assessment procedure.

3. The MDCG, following the consultation of the ACMD shall issue a MDCG opinion on the documents referred to in

paragraph 2 at the latest 60 days after its submission. Within that period and at the latest 30 days after submission, the ACMD through the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the documents referred to in paragraph 2. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. In its opinion the MDCG shall take into account the clinical assessment of the ACMD. The MDCG may recommend modifications of the documents referred to in paragraph 2.

5. The MDCG shall inform the Commission, the Special notified body and the manufacturer of its opinion.

6. Within 15 days after receipt of the opinion referred to in paragraph 5, the Special notified body shall indicate whether or not it agrees with the opinion of the MDCG. In the latter case, it may give written notice to the MDCG that it wishes to request a re-examination of the opinion. In that case, the Special notified body shall forward to the MDCG the detailed grounds for the request within 30 days after receipt of the opinion. The MDCG shall immediately transmit this information to the Commission

Within 30 days following receipt of the grounds for the request, the MDCG shall re-examine its opinion. The reasons for the conclusion reached shall be annexed to the final opinion.

7. Immediately after its adoption, the MDCG shall send its final opinion to the

Commission, the Special notified body and the manufacturer.

8. In case of a favourable MDCG opinion, the special notified body may proceed with the certification.

However if the favourable MDCG opinion is dependent on the application of specific measures (e.g. adaptation of the post-market clinical follow-up plan, certification with a time limit), the special notified body shall issue the certificate of conformity only on condition that those measures are fully implemented.

Following the adoption of a favourable opinion, the Commission shall always explore the possibility of adopting, common technical standards for the device or group of devices concerned and adopt them where possible.

In case of an unfavourable MDCG opinion, the special notified body shall not deliver the certificate of conformity. Nevertheless, the special notified body may submit new information in response to the explanation included in the MDCG assessment. If the new information is substantially different to that which has been previously submitted the MDCG shall reassess the application.

At the request of the manufacturer, the Commission shall organise a hearing allowing discussion on the scientific grounds for the unfavourable scientific assessment and any action that the manufacturer may take or data that may be submitted to address the MDCG concerns.

9. Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to determine, specific categories or groups of devices, other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply during a predefined period of

time.

Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.

10. The Commission shall make a summary of the opinion referred to in paragraphs 6 and 7 accessible to the public. It shall not disclose any personal data or information of a commercially confidential nature.

11. The Commission shall set up the technical infrastructure for the data-exchange by electronic means between the MDCG, the Special notified bodies and the ACMD and between the ACMD and itself for the purposes of this Article.

12. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

13. The company concerned shall not be charged for the additional costs due to this assessment.

Amendment 153

Proposal for a regulation Chapter VI – title

Text proposed by the Commission

Chapter **VI**
Clinical evidence

Amendment

Chapter **V***
Clinical evidence

** As a consequence of this amendment, this Chapter will cover Articles 47, 48, 49, **49a**, 50, 51, 52, 53, 54, 55, 57, 58*

Amendment 154

Proposal for a regulation

Article 47 – paragraph 1

Text proposed by the Commission

1. The demonstration of conformity with the general safety and performance requirements set out in Annex I, under normal conditions of use, shall be based on clinical evidence.

Amendment

1. The demonstration of conformity with the general safety and performance requirements set out in Annex I, under normal conditions of use, shall be based on clinical evidence, ***or additional safety data for general safety and performance requirements not covered by clinical evidence.***

Amendment 155

Proposal for a regulation

Article 47 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Where the manufacturer claims and/or describes a clinical use, evidence attesting to that use shall constitute part of the requirements.

Amendment 156

Proposal for a regulation

Article 47 – paragraph 4 – subparagraph 2 (new)

Text proposed by the Commission

Amendment

Exemption from demonstration of conformity with general safety and performance requirements based on clinical data under the first subparagraph shall be subject to prior approval by the competent authority.

Amendment 157

Proposal for a regulation

Article 47 – paragraph 5

Text proposed by the Commission

Amendment

5. The scientific validity data, the analytical performance data and, where

5. The scientific validity data, the analytical performance data and, where

applicable, the clinical performance data shall be summarised as part of a clinical evidence report referred to in Section 3 of Part A of Annex XII. The clinical evidence report shall be included *or fully referenced* in the technical documentation referred to in Annex II relating to the device concerned.

applicable, the clinical performance data shall be summarised as part of a clinical evidence report referred to in Section 3 of Part A of Annex XII. The clinical evidence report shall be included in the technical documentation referred to in Annex II relating to the device concerned.

Amendment 158

Proposal for a regulation

Article 48 – paragraph 1 – point a

Text proposed by the Commission

(a) to verify that, under normal conditions of use, the devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of an *in vitro* diagnostic medical device referred to in number (2) of Article 2, and achieve the performance intended as specified by the manufacturers;

Amendment

(a) to verify that, under normal conditions of use, the devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of an *in vitro* diagnostic medical device referred to in number (2) of Article 2, and achieve the performance intended as specified by the manufacturers *or sponsor*;

Amendment 159

Proposal for a regulation

Article 48 – paragraph 1 – point b

Text proposed by the Commission

(b) to verify *that devices achieve* the intended benefits to the patient *as specified by the manufacturer*;

Amendment

(b) to verify *the clinical safety and efficacy of the device, including* the intended benefits to the patient, *when used for the intended purpose, in the target population and in accordance with the instructions of use*;

Amendment 160

Proposal for a regulation

Article 48 – paragraph 4

Text proposed by the Commission

4. All clinical performance studies shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such clinical performance

Amendment

4. All clinical performance studies shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such clinical performance

studies are protected and that the clinical data generated in the clinical performance study are going to be reliable and robust.

studies are protected and that the clinical data generated in the clinical performance study are going to be reliable and robust. ***Such studies shall not be conducted if the risks associated with the investigation are not medically justifiable in terms of the potential benefits of the device.***

Amendment 161

Proposal for a regulation Article 48 – paragraph 6

Text proposed by the Commission

6. For interventional clinical performance studies, as defined in number (37) of Article 2, and for other clinical performance studies, where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies, the requirements set out in Articles 49 to 58 and in Annex XIII shall apply, in addition to the obligations laid down in this Article.

Amendment

6. For interventional clinical performance studies, as defined in number (37) of Article 2, and for other clinical performance studies, where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies, the requirements set out in Articles 49 to 58 and in Annex XIII shall apply, in addition to the obligations laid down in this Article. ***The Commission shall be empowered to adopt delegated acts in accordance with Article 85 concerning the provision of a list with negligible risks, which allows a derogation to be made from the relevant Article.***

Amendment 162

Proposal for a regulation Article 49 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. The sponsor of a clinical performance study shall submit an application to the Member State(s) in which the study is to be conducted accompanied by the documentation referred to in Annex XIII. Within *six* days after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete.

Amendment

2. The sponsor of a clinical performance study shall submit an application to the Member State(s) in which the study is to be conducted accompanied by the documentation referred to in Annex XIII. Within ***14*** days after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete.

In case of more than one Member State concerned, where a Member State disagrees with the coordinating Member State on whether the clinical performance study should be approved, on grounds other than intrinsically national, local or ethical concerns, the Member States concerned shall make an attempt to agree on a conclusion. If no conclusion is found, the Commission shall take a decision after having consulted the Member States concerned, and if appropriate, having taken advice from the MDCG.

In case where the concerned Member States object to the clinical performance study for intrinsically national, local or ethical concerns the clinical performance study should not take place in the Member States concerned.

Amendment 163

Proposal for a regulation

Article 49 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Where the Member State finds that the clinical performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of *six* days for the sponsor to comment or to complete the application.

Amendment

Where the Member State finds that the clinical performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of *ten* days for the sponsor to comment or to complete the application.

Amendment 164

Proposal for a regulation

Article 49 – paragraph 3 – subparagraph 3

Text proposed by the Commission

Where the Member State has not notified the sponsor according to paragraph 2 within *three* days following receipt of the comments or of the completed application, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be

Amendment

Where the Member State has not notified the sponsor according to paragraph 2 within *seven* days following receipt of the comments or of the completed application, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be

considered complete.

considered complete.

Amendment 165

Proposal for a regulation

Article 49 – paragraph 5 – point c

Text proposed by the Commission

c) after the expiry of **35** days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.

Amendment

c) after the expiry of **60** days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.

Amendment 166

Proposal for a regulation

Article 49 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. Member States shall ensure that a clinical performance study is suspended, cancelled or temporarily interrupted if in the light of new facts it would no longer be approved by the competent authority or if it would no longer receive a favourable opinion from the ethics committee.

Amendment 167

Proposal for a regulation

Article 49 – paragraphs 6 a to 6 e (new)

Text proposed by the Commission

Amendment

6a. Every step in the clinical performance study, from first consideration of the need and justification for the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, such as those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th World Medical Assembly in Helsinki in 1964 and last amended by the 59th World Medical

Association General Assembly in Seoul in 2008.

6b. Authorisation by the Member State concerned for conducting a clinical performance study under this Article shall be granted only after examination and approval by an independent ethics committee in accordance with the World Medical Association's Declaration of Helsinki.

6c. The examination of the Ethics Committee shall cover in particular the medical justification for the study, the consent of the test subjects participating in the clinical performance study following the provision of full information about the clinical performance study and the suitability of the investigators and investigation facilities.

The ethics committee shall act in accordance with the respective laws and regulations of the country or countries in which the study is to be conducted and shall abide by all relevant international norms and standards. It shall also work with such efficiency as to enable the Member State concerned to comply with the procedural deadlines set out in this Chapter.

The ethics committee shall be made up of an appropriate number of members, who together are in possession of the relevant qualifications and experience in order to be able to assess the scientific, medical and ethical aspects of the clinical investigation under scrutiny.

The members of the Ethics Committee assessing the application for a clinical performance study shall be independent from the sponsor, the institution of the performance study site, and the investigators involved, as well as free of any other undue influence. Names, qualifications, and declaration of interest of the assessors of the application shall be made publicly available.

6d. Member States shall take the necessary measures to establish Ethics

Committees in the field of clinical performance studies where such committees do not exist, and to facilitate their work.

6e. The Commission shall facilitate cooperation of ethics committees and the sharing of best practices on ethical issues including the procedures and principles of ethical assessment.

The Commission shall develop guidelines on patient involvement in ethics committees, drawing upon existing good practices.

Amendment 168

Proposal for a regulation Article 49 a (new)

Text proposed by the Commission

Amendment

Article 49a

Supervision by Member States

- 1. Member States shall appoint inspectors to supervise compliance with this Regulation and shall ensure that those inspectors are adequately qualified and trained.*
- 2. Inspections shall be conducted under the responsibility of the Member State where the inspection takes place.*
- 3. Where a Member State intends to carry out an inspection with regard to one or several interventional clinical performance studies which are conducted in more than one Member State, it shall notify its intention to the other Member States concerned, the Commission and the EMA, through the Union portal, and shall inform them of its findings after the inspection.*
- 4. The MDCG shall coordinate cooperation on inspections between Member States and on inspections conducted by Member States in third countries.*
- 5. Following an inspection, the Member*

State under whose responsibility the inspection has been conducted shall draw up an inspection report. That Member State shall make the inspection report available to the sponsor of the relevant clinical trial and shall submit the inspection report through the Union portal to the Union database. When making the inspection report available to the sponsor, the Member State concerned shall ensure that confidentiality is protected.

6. The Commission shall specify the details for the arrangement of the inspection procedures by means of implementing acts in accordance with Article 85.

Amendment 169

Proposal for a regulation

Article 50 – paragraph 1 – point g a (new)

Text proposed by the Commission

Amendment

(g a) the methodology to be used, the number of subjects involved and the intended result of the study.

Amendment 170

Proposal for a regulation

Article 51

Text proposed by the Commission

Amendment

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies to create the single identification numbers for such clinical performance studies referred to in Article 49(1) and to collate and process the following information:

- (a) the registration of clinical performance studies in accordance with Article 50;
- (b) the exchange of information between

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies to create the single identification numbers for such clinical performance studies referred to in Article 49(1) and to collate and process the following information:

- (a) the registration of clinical performance studies in accordance with Article 50;
- (b) the exchange of information between

the Member States and between them and the Commission in accordance with Article 54;

(c) the information related to clinical performance studies conducted in more than one Member State in case of a single application in accordance with Article 56;

(d) the reports on serious adverse events and device deficiencies referred to in Article 57(2) in case of single application in accordance with Article 56.

2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article [...] of Regulation (EU) No [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 50, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 determining which other information regarding clinical performance studies collated and processed in the electronic system shall be publicly

the Member States and between them and the Commission in accordance with Article 54;

(c) the information related to clinical performance studies conducted in more than one Member State in case of a single application in accordance with Article 56;

(d) the reports on serious adverse events and device deficiencies referred to in Article 57(2) in case of single application in accordance with Article 56.

(da) the clinical performance study report and summary submitted by the sponsor in accordance with Article 55(3)

2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article [...] of Regulation (EU) No [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 50 ***and in points (d) and (da) of Article 51***, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission. ***The Commission shall also ensure that healthcare professionals have access to the electronic system.***

The information referred to in points (d) and (da) of Article 51 shall be accessible to the public in accordance with Article 50(3) and (4).

2a. Upon a reasoned request, all information on a specific in vitro diagnostic medical device available in the electronic system shall be made accessible to the party requesting it, save where the confidentiality of all or parts of the information is justified in accordance with Article 50(3).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 determining which other information regarding clinical performance studies collated and processed in the electronic system shall be publicly

accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No [Ref. of future Regulation on clinical trials]. Article 50(3) and (4) shall apply.

accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No [Ref. of future Regulation on clinical trials]. Article 50(3) and (4) shall apply.

Amendment 171

Proposal for a regulation Article 54 – paragraph 1

Text proposed by the Commission

1. Where a Member State has refused, suspended or terminated a clinical performance study, or has called for a substantial modification or temporary halt of a clinical performance study, or has been notified by the sponsor of the early termination of a clinical performance study on safety grounds, that Member State shall communicate its decision and the grounds **therefor** to all Member States and the Commission by means of the electronic system referred to in Article 51.

Amendment

1. Where a Member State has refused, suspended or terminated a clinical performance study, or has called for a substantial modification or temporary halt of a clinical performance study, or has been notified by the sponsor of the early termination of a clinical performance study on safety **or efficacy** grounds, that Member State shall communicate **such facts and** its decision and the grounds **for that decision** to all Member States and the Commission by means of the electronic system referred to in Article 51.

Amendment 172

Proposal for a regulation Article 55 – paragraph 1

Text proposed by the Commission

1. If the sponsor has temporarily halted a clinical performance study on safety grounds, he shall inform the Member States concerned within 15 days of the temporary halt.

Amendment

1. If the sponsor has temporarily halted a clinical performance study on safety **or efficacy** grounds, he shall inform the Member States concerned within 15 days of the temporary halt.

Amendment 173

Proposal for a regulation Article 55 – paragraph 2 – subparagraph 1

Text proposed by the Commission

The sponsor shall notify each Member State concerned of the end of a clinical performance study in relation to that

Amendment

The sponsor shall notify each Member State concerned of the end of a clinical performance study in relation to that

Member State, providing a justification in the event of early termination. That notification shall be made within 15 days from the end of the clinical performance study in relation to that Member State.

Member State, providing a justification in the event of early termination, *so that all Member States can inform sponsors conducting similar clinical performance studies at the same time within the Union of the results of that clinical performance study*. That notification shall be made within 15 days from the end of the clinical performance study in relation to that Member State.

Amendment 174

Proposal for a regulation

Article 55 – paragraph 2 – subparagraph 2

Text proposed by the Commission

If the study is conducted in more than one Member State, the sponsor shall notify all Member States concerned of the overall end of the clinical performance study. That notification shall be made within 15 days from the overall end of the clinical performance study.

Amendment

If the study is conducted in more than one Member State, the sponsor shall notify all Member States concerned of the overall end of the clinical performance study. *Information on the reasons for the early termination of the clinical performance study shall also be provided to all Member States, so that all Member States can inform sponsors conducting similar clinical performance studies, at the same time within the Union, of the results of that the clinical performance study*. That notification shall be made within 15 days from the overall end of the clinical performance study.

Amendment 175

Proposal for a regulation

Article 55 - paragraphs 3 and 3 a (new)

Text proposed by the Commission

3. *Within* one year from the end of the clinical performance study, the sponsor shall submit to the Member States concerned *a summary of* the results of the clinical performance study in form of a clinical performance study report referred to in Section 2.3.3 of Part A of Annex XII. Where, for scientific reasons, it is not possible to submit the clinical performance study report within one year, it shall be

Amendment

3. *Irrespective of the outcome of the clinical performance study, within* one year from the end of the clinical performance study *or from its early termination*, the sponsor shall submit to the Member States concerned the results of the clinical performance study in form of a clinical performance study report referred to in Section 2.3.3 of Part A of Annex XII.. *It shall be accompanied by a summary*

submitted as soon as it is available. In this case, the clinical performance study protocol referred to in Section 2.3.2 of Part A of Annex XII shall specify when the results of the clinical performance study are going to be submitted, together with **an explanation**.

presented in terms that are easily understandable to a layperson. Both the report and the summary shall be submitted by the sponsor by means of the electronic system referred to in Article 51.

Where, for **justified** scientific reasons, it is not possible to submit the clinical performance study report within one year, it shall be submitted as soon as it is available. In this case, the clinical performance study protocol referred to in Section 2.3.2 of Part A of Annex XII shall specify when the results of the clinical performance study are going to be submitted, together with **a justification**.

3a. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 in order to define the content and structure of the layperson's summary.

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 in order to establish rules for the communication of the clinical performance study report.

For cases where the sponsor decides to share raw data on a voluntary basis, the Commission shall produce guidelines for the formatting and sharing of that data.

Amendment 176

Proposal for a regulation Article 56 – paragraph 2

Text proposed by the Commission

2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. If that Member State does not wish to be the coordinating Member State, it shall agree, within six days of submission of the single application, with another Member State concerned that the latter shall be the coordinating Member State. If no other Member State accepts to be the coordinating Member State, the Member

Amendment

2. The Member States concerned shall agree, within six days of submission of the single application, **which** Member State shall be the coordinating Member State. **Member States and the Commission shall agree, in the framework of the attributions of the Medical Devices Coordination Group, on clear rules for designating the coordinating Member State.**

State proposed by the sponsor shall be the coordinating Member State. If another Member State than the one proposed by the sponsor becomes coordinating Member State, the deadlines referred to in Article 49(2) shall start on the day following the acceptance.

Amendment 177

Proposal for a regulation Article 56 - paragraph 5

Text proposed by the Commission

Amendment

5. For the purpose of Article 55(3), the sponsor shall submit the clinical performance study report to the Member States concerned by means of the electronic system referred to in Article 51.

deleted

Amendment 178

Proposal for a regulation Article 57 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission

Amendment

(a) *a serious* adverse event that has a causal relationship with the device for performance evaluation, the comparator or the study procedure or where such causal relationship is reasonably possible;

(a) *any* adverse event that has a causal relationship with the device for performance evaluation, the comparator or the study procedure or where such causal relationship is reasonably possible;

Amendment 179 Proposal for a regulation Chapter VII – title

Text proposed by the Commission

Amendment

Chapter VII

Chapter VIII*

Vigilance and market surveillance

Vigilance and market surveillance

** As a consequence of this amendment, this Chapter will cover Articles 59 to 73.*

Amendment 180

Proposal for a regulation Article 59

1. Manufacturers of devices, other than devices for performance evaluation, shall report through the electronic system referred to in Article 60 the following::

(a) any *serious* incident in respect of devices made available on the Union market;

(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market if the reason for the field safety corrective action is not limited to the device made available in the third country.

Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible. The time period for reporting shall take account of the severity of the incident. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

2. For similar *serious* incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 60(5) have agreed with the manufacturer on the

1. Manufacturers of devices, other than devices for performance evaluation, shall report through the electronic system referred to in Article 60 the following::

(a) any incident, ***including date and place of incident, with an indication of whether it is serious in accordance with the definition under Article 2,*** in respect of devices made available on the Union market; ***where available, the manufacturer shall include information on the patient or user and healthcare professional involved in the incident;***

(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market if the reason for the field safety corrective action is not limited to the device made available in the third country.

Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible. The time period for reporting shall take account of the severity of the incident. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

2. For similar incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 60(5) have agreed with the manufacturer on the format,

format, content and frequency of the periodic summary reporting.

3. The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected *serious* incidents referred to in point (a) of paragraph 1.

They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall ***take the necessary steps to ensure that*** the manufacturer of the device concerned ***is informed of the incident***. The manufacturer shall ensure the appropriate follow-up.

The Member States shall ***coordinate between them the development of*** standard ***web-based structured*** forms for reporting of *serious* incidents by healthcare professionals, users and patients.

4. Health institutions manufacturing and using devices referred to in Article 4(4) shall report any *serious* incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the health institution is located.

content and frequency of the periodic summary reporting.

3. The Member States shall take all appropriate measures, ***including targeted information campaigns***, to encourage ***and enable*** healthcare professionals, ***including doctors and pharmacists***, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They ***shall inform the Commission of those measures***.

The competent authorities of the Member States shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall ***inform*** the manufacturer of the device concerned ***without delay***. The manufacturer shall ensure the appropriate follow-up.

The competent authority of a Member State shall notify the reports referred to in the first subparagraph to the electronic system referred to in Article 60 without delay, unless the same incident has already been reported by the manufacturer.

The ***Commission, in cooperation with the Member States and in consultation with the relevant stakeholders***, shall ***develop*** standard forms for ***electronic and non-electronic*** reporting of incidents by healthcare professionals, users and patients.

4. Health institutions manufacturing and using devices referred to in Article 4(4) shall ***immediately*** report any incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the health institution is located.

Amendment 181

Proposal for a regulation

Article 60

Text proposed by the Commission

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

(a) the reports by manufacturers on *serious* incidents and field safety corrective actions referred to in Article 59(1);

(b) the periodic summary reports by manufacturers referred to in Article 59(2);

(c) the reports by competent authorities on *serious* incidents referred to in the second subparagraph of Article 61(1)

(d) the reports by manufacturers on trends referred to in Article 62;

(e) the field safety notices by manufacturers referred to in Article 61(4);

(f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 61(3) and (6).

2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies.

3. The Commission shall ensure that *healthcare professionals and* the public *have* appropriate *levels* of access to the

Amendment

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

(a) the reports by manufacturers on incidents and field safety corrective actions referred to in Article 59(1);

(b) the periodic summary reports by manufacturers referred to in Article 59(2);

(c) the reports by competent authorities on incidents referred to in the second subparagraph of Article 61(1)

(d) the reports by manufacturers on trends referred to in Article 62;

(e) the field safety notices by manufacturers referred to in Article 61(4);

(f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 61(3) and (6).

(f a) the reports by competent authorities on serious incidents and field safety corrective actions taken within health institutions involving devices referred to in Article 4(4)

2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission, to the notified bodies, *to healthcare professionals and also to manufacturers where the information pertains to their own product.*

3. The Commission shall ensure that the public *has an* appropriate *level* of access to the electronic system. *Where information*

electronic system.

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on *serious* incidents and field safety corrective actions referred to in points (a) and (b) of Article 59(1), the periodic summary reports referred to in Article 59(2), the reports on *serious* incidents referred to in the second subparagraph of Article 61(1) and the trend reports referred to in Article 62 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States

- (a) the Member State where the incident occurred;
- (b) the Member State where the field safety corrective action is being or is to be undertaken;
- (c) the Member State where the manufacturer has his registered place of business;
- (d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 43 for the device in question, is established.

is requested on a specific in vitro diagnostic medical device, that information shall be made available without delay and within 15 days at the latest.

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on incidents and field safety corrective actions referred to in points (a) and (b) of Article 59(1), the periodic summary reports referred to in Article 59(2), the reports on incidents referred to in the second subparagraph of Article 61(1) and the trend reports referred to in Article 62 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States

- (a) the Member State where the incident occurred;
- (b) the Member State where the field safety corrective action is being or is to be undertaken;
- (c) the Member State where the manufacturer has his registered place of business;
- (d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 43 for the device in question, is established.

5a. The reports and information referred to in Article 60(5), shall also be automatically transmitted for the device in question via the electronic system to the notified body that issued the certificate in accordance with Article 43.

Amendment 182

Proposal for a regulation

Article 61 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer.

Amendment

1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer. ***The competent authority shall take into account the views of all relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.***

Amendment 183

Proposal for a regulation

Article 61 – paragraph 1 – subparagraph 2

Text proposed by the Commission

If in the case of reports received in accordance with Article 59(3) the competent authority ascertains that the reports relate to a serious incident it shall notify without delay those reports to the electronic system referred to in Article 60, unless the same incident has already been reported by the manufacturer.

Amendment

deleted

Amendment 184

Proposal for a regulation

Article 61 – paragraph 2

Text proposed by the Commission

2. The national competent authorities shall carry out a risk assessment with regard to reported serious incidents or field safety corrective actions, taking into account

Amendment

2. The national competent authorities shall carry out a risk assessment with regard to reported serious incidents or field safety corrective actions, taking into account

criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action. They shall monitor the manufacturer's investigation of the incident.

criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action. They shall monitor the manufacturer's investigation of the *serious* incident.

Amendment 185

Proposal for a regulation

Article 65 – paragraphs 1, 1 a to 1 e (new) and 2

Text proposed by the Commission

1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, *where necessary and justified*, enter the premises of economic operators and take the necessary samples of devices. They may destroy or otherwise render inoperable devices presenting a *serious* risk where they deem it necessary.

Amendment

1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and enter *and inspect* the premises of economic operators and take the necessary samples of devices *for analysis by an official laboratory*. They may destroy or otherwise render inoperable devices presenting a risk where they deem it necessary.

1a. The competent authorities shall designate inspectors who shall be empowered to carry out the checks referred to in paragraph 1. The checks shall be carried out by the inspectors of the Member State in which the economic operator is located. Those inspectors may be assisted by experts appointed by the competent authorities.

1b. Unannounced inspections may also be carried out. The organisation and implementation of such inspections must always take account of the principle of proportionality, particularly with reference to the hazard potential of a particular product.

1c. Following each inspection carried out under paragraph 1, the competent authority shall draw up a report on compliance by the economic operator inspected with the legal and technical requirements applicable under this Regulation and any corrective actions needed.

1d. The competent authority which carried out the inspection shall communicate the content of this report to the inspected economic operator. Before adopting the report, the competent authority shall give the inspected economic operator the opportunity to submit comments. The final inspection report as referred to in paragraph 1b shall be entered into the electronic system provided for in Article 66.

1e. Without prejudice to any international agreements concluded between the Union and third countries, checks as referred in paragraph 1 can also take place in the premises of an economic operator located in a third country, if the device is intended to be made available on the Union market.

2. The Member States shall periodically review and assess the **functioning** of their surveillance **activities**. Such reviews and assessments shall be carried out at least every **four** years and the results thereof shall be communicated to the other Member States and the Commission. The Member **State concerned** shall make a summary of the results accessible to the public.

2. The Member States shall **draw up strategic surveillance plans covering their planned surveillance activities, as well as the human and material resources needed to carry those activities out**. Member States shall periodically review and assess the **implementaion** of their surveillance **plans**. Such reviews and assessments shall be carried out at least every **two** years and the results thereof shall be communicated to the other Member States and the Commission. **The Commission may make recommendations for adjustments to the surveillance plans**. The Member States shall make a summary of the results **and of**

the Commission's recommendations
accessible to the public.

Amendment 186

Proposal for a regulation Article 66 – paragraph 2

Text proposed by the Commission

2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States and to the Commission.

Amendment

2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States, *to the Commission, to the Agency* and to *healthcare professionals*. *The Commission shall also ensure that the public has an appropriate level of access to the electronic system. In particular, it shall ensure that, where information is requested on a specific in vitro diagnostic medical device, it is made available without delay and within 15 days. The Commission, in consultation with the Medical Devices Coordination Group, shall provide an overview of this information, every 6 months, for the public and healthcare professionals. This information shall be accessible through the European databank referred to in Article 25.*

Amendment 187

Proposal for a regulation Chapter VIII – title

Text proposed by the Commission

Chapter **VIII**

Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers

Amendment

Chapter **IX***

Cooperation between Member States, Medical Device Coordination Group, **Medical Device Advisory Committee**, EU reference laboratories, device registers

** As a consequence of this amendment, this Chapter will cover Articles 74 to 79.*

Amendment 188

Proposal for a regulation

Article 76 a (new)

Text proposed by the Commission

Amendment

Article 76a

Medical Device Advisory Committee

The Medical Device Advisory Committee (MDAC) established in accordance with the conditions and modalities defined in Article 78a of Regulation (EU) No ... shall carry out, with the support of the Commission the tasks assigned to it by this Regulation.*

** OJ: please insert the reference and date etc.*

Amendment 260

Proposal for a regulation

Article 76 b (new)

Text proposed by the Commission

Amendment

Article 76b

Assessment Committee for Medical Devices

1. An ACMD is hereby established, under the principles of highest scientific competence, impartiality, transparency and to avoid potential conflicts of interest.

2. When undertaking a clinical assessment for a specific device, the ACMD shall be composed of:

- a minimum of 5 clinical experts in the field of which a clinical assessment and recommendation have been requested;*
- one representative of the EMA;*
- one representative of the Commission;*
- one representative of patients'*

organisations appointed by the Commission in a transparent manner after a call for interest, for a three-year term which may be renewed.

The ACMD shall meet on request from the MDCG and Commission, and its meetings shall be chaired by a Commission representative.

The Commission shall ensure that the composition of the ACMD corresponds to the expertise needed for the purpose of its clinical assessment and recommendation.

The Commission shall be responsible for providing the secretariat of this Committee.

3. The Commission shall establish a pool of clinical experts in the medical fields relevant to in vitro diagnostic medical devices being assessed by the ACMD.

In order to undertake the clinical assessment and recommendation procedure, each Member State may propose one expert, following a Union-wide call for expression of interest with a clear definition by the Commission of the requested profile. The publication of the call shall be widely advertised. Each expert shall be approved by the Commission and listed for a three-year term which may be renewed.

The Members of the ACMD shall be chosen for their competence and experience in the corresponding field. They shall perform their tasks with impartiality and objectivity. They shall be completely independent and shall neither seek nor take instructions from any government, notified body or manufacturer. Each member shall draw up a declaration of interests which shall be made publicly available.

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article

85 amending or supplementing the fields referred to in the first subparagraph of this paragraph.

4. The ACMD shall fulfil the tasks defined in Article 44a. When adopting its clinical assessment and recommendation, the members of the ACMD shall use their best endeavours to reach consensus. If consensus cannot be reached, the ACMD shall decide by the majority of their members. Any diverging opinion shall be annexed to the ACMD opinion.

5. The ACMD shall establish its rules of procedure which shall, in particular, lay down procedures for the following:

- the adoption of opinions, including in case of urgency;

- the delegation of tasks to reporting and co-reporting members.

Amendment 261

Proposal for a regulation Article 77 – point a

Text proposed by the Commission

Amendment

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(-a) to provide regulatory opinions on the basis of a scientific assessment on certain types of in vitro diagnostic medical devices pursuant to Article 44a;

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(aa) to establish and document the high level principles of competence and qualification and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing). The qualification criteria shall address the various functions within the conformity assessment process as well as the devices,

technologies and areas covered by the scope of designation;

(ab) to review and approve the criteria of the competent authorities of Member States in respect of point (aa);

(ac) to oversee the coordination group of Notified Bodies as specified in Article 37;

(ad) to support the Commission in providing an overview of vigilance data and market surveillance activities, including any preventive health protection measures taken, on a 6-monthly basis. This information shall be accessible through the European databank in Article 25;

Amendments 190

Proposal for a regulation

Article 77 – point b

Text proposed by the Commission

Amendment

(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 42;

deleted

Amendment 191

Proposal for a regulation

Article 78 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) to carry out appropriate tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 5.7 of Annex VIII and in Section 5.1 of Annex X;

*(b) to carry out appropriate **laboratory** tests on samples of manufactured class D devices on request of competent authorities on samples collected during market surveillance activities under Article 65 and of notified bodies on samples collected during unannounced inspections under Annex VIII section 4.4;*

Amendment 192

Proposal for a regulation

Article 78 – paragraph 2 – point d

Text proposed by the Commission

Amendment

(d) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices;

(d) to provide scientific advice **and technical assistance** regarding **the definition of** the state of the art in relation to specific devices, or a category or group of devices;

Amendment 193

Proposal for a regulation

Article 78 – paragraph 2 – point f

Text proposed by the Commission

Amendment

(f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures **and** market surveillance;

(f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures, **in particular for batch verification of class D devices and for** market surveillance;

Amendment 194

Proposal for a regulation

Article 78 – paragraph 2 – point i

Text proposed by the Commission

Amendment

(i) to contribute to the development of **standards at international level;**

(i) to contribute to the development of **common technical specifications (CTS) and of international standards**

Amendment 195

Proposal for a regulation

Article 78 – paragraph 3 – point a

Text proposed by the Commission

Amendment

(a) to have appropriately qualified staff with adequate knowledge and experience in the field of the in vitro diagnostic medical devices for which they are designated;

(a) to have appropriately qualified staff with adequate knowledge and experience in the field of the in vitro diagnostic medical devices for which they are designated; **appropriate knowledge and experience shall be based on:**

(i) experience of assessing high-risk IVDs and of carrying out the relevant

laboratory tests;

(ii) in-depth knowledge of high-risk in-vitro diagnostic medical devices and relevant technologies;

(iii) proven laboratory experience in one of the following areas: testing or calibration laboratory, supervisory authority or institution, national reference laboratory for class D devices, quality control of in-vitro diagnostic medical devices, development of reference materials for IVDs, calibration of diagnostic medical devices; laboratories or blood banks which experimentally assess and use high-risk IVDs or, where applicable, manufacture them in-house;

(iv) knowledge and experience of product or batch testing, quality checks, design, manufacture and use of IVDs;

(v) knowledge of the health risks faced by patients, their partners and recipients of blood/organ/tissue donations/preparations associated with the use and, in particular, malfunctioning of high-risk IVDs;

(vi) knowledge of this Regulation and of applicable laws, rules and guidelines, knowledge of the Common Technical Specifications (CTS), applicable harmonized standards, product-specific requirements and relevant guidance documents;

(vii) participation in relevant external and internal quality assessment schemes organised by international or national organisations.

Amendment 196

Proposal for a regulation Article 78 – paragraph 5

Text proposed by the Commission

5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they *may* be required to pay fees to wholly *or partially* cover the costs

Amendment

5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they *shall* be required to pay fees to wholly cover the costs incurred by

incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.

that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.

Amendment 197

Proposal for a regulation Article 79 – paragraph 1

Text proposed by the Commission

The Commission and the Member States shall take all appropriate measures to **encourage** the establishment of registers for **specific types of** devices to gather post-market experience related to the use of such devices. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.

Amendment

The Commission and the Member States shall take all appropriate measures to **ensure** the establishment of registers for **in vitro diagnostic** devices to gather post-market experience related to the use of such devices. **Registers for class C and D devices shall be systematically established.** Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.

Amendment 200

Proposal for a regulation Chapter IX – title

Text proposed by the Commission

Chapter IX

Confidentiality, data protection, funding, penalties

Amendment

Chapter X*

Confidentiality, data protection, funding, penalties

** As a consequence of this amendment, this Chapter will cover Articles 80 to 83.*

Amendment 198

Proposal for a regulation Article 82 – paragraph 1

Text proposed by the Commission

This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. They shall inform the Commission and the other

Amendment

This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is **comparable and** set in a transparent manner and on the basis of cost recovery principles. They shall inform the

Member States at least three months before the structure and level of fees is to be adopted.

Commission and the other Member States at least three months before the structure and level of fees is to be adopted.

Amendment 199

Proposal for a regulation

Article 83 – paragraph 1

Text proposed by the Commission

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of this Regulation] and shall notify it without delay of any subsequent amendment affecting them.

Amendment

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. ***The dissuasive nature of the penalty shall be determined in relation to the financial benefit obtained as a result of the infringement.*** The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of this Regulation] and shall notify it without delay of any subsequent amendment affecting them.

Amendment 201

Proposal for a regulation

Chapter X – title

Text proposed by the Commission

Chapter X
Final provisions

Amendment

Chapter XI*
Final provisions

** As a consequence of this amendment, this Chapter will cover Articles 84 to 90.*

Amendment 202

Proposal for a regulation

Article 90 – paragraphs 2 and 3

Text proposed by the Commission

2. It shall apply from [**five** years after entry into force].

Amendment

2. It shall apply from [**three** years after entry into force].

3. By way of derogation from paragraph 2, the following shall apply:

(a) Article 23(2) *and* (3) *and* Article 43(4) shall apply from [18 months after date of application referred to in paragraph 2];

(b) Articles 26 to 38 shall apply from [six months after entry into force]. However, prior to [date of application as referred to in paragraph 2], the obligations on notified bodies emanating from the provisions in Articles 26 to 38 shall apply only to those bodies which submit an application for notification in accordance with Article 29 of this Regulation.

3. By way of derogation from paragraph 2, the following shall apply:

(a) Article 23(1) shall apply from [30 months after entry into force];

(b) Articles 26 to 38 shall apply from [six months after entry into force]. However, prior to [date of application as referred to in paragraph 2], the obligations on notified bodies emanating from the provisions in Articles 26 to 38 shall apply only to those bodies which submit an application for notification in accordance with Article 29 of this Regulation.

(ba) Article 74 shall apply from ... ;*

** OJ: please insert the date: six months after the entry into force of this Regulation.*

(bb) Articles 75 to 77 shall apply from... ;*

** OJ: please insert the date: 12 months after the entry into force of this Regulation.*

(bc) Article 59 to 64 shall apply from... ;*

** OJ: please insert the date: 24 months after the entry into force of this Regulation.*

(bd) Article 78 shall apply from*

** OJ: please insert the date: 24 months after the entry into force of this Regulation*

3a. The implementing acts referred to in Articles 31(4), 40(9), 42(8), 46(2) and Articles 58 and 64 shall be adopted within*

** OJ: please insert the date: 12 months after the entry into force of this Regulation.*

Amendment 203

Proposal for a regulation

Annex I – part II – point 6.1 – point b

Text proposed by the Commission

(b) the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive and negative predictive value, likelihood ratio, expected values in normal or affected populations.

Amendment

(b) the clinical performance, ***including measures of clinical validity*** such as diagnostic sensitivity, diagnostic specificity, positive and negative predictive value, likelihood ratio, expected values in normal or affected populations; ***and, where appropriate, measures of clinical utility. In the case of companion diagnostics, evidence of the clinical utility of the device for the intended purpose (selection of patients with a previously diagnosed condition or predisposition eligible for a targeted therapy) is required. For a companion diagnostic, the manufacturer should supply clinical evidence relating to the impact of a positive or negative test on (1) patient care; and (2) health outcomes, when used as directed with the stated therapeutic intervention.***

Amendment 204

Proposal for a regulation

Annex I – part II – point 16

Text proposed by the Commission

16. Protection against the risks posed by devices intended by the manufacturer for self-testing ***or near-patient testing***

16.1 The devices intended for self-testing ***or near-patient testing*** shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply.

16.2 The devices intended for self-testing

Amendment

16. Protection against the risks posed by devices intended by the manufacturer for self-testing

16.1 The devices intended for self-testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply.

16.2 The devices intended for self-testing

or near-patient testing shall be designed and manufactured in such a way as to

- ensure that the device is easy to use by the intended user at all stages of the procedure; and
- reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.

16.3 The devices intended for self-testing *and near-patient testing* shall, where reasonably possible, include a procedure by which the intended user can:

- verify that, at the time of use, the device will perform as intended by the manufacturer; and
- be warned if the device has failed to provide a valid result.

shall be designed and manufactured in such a way as to

- ensure that the device is easy to use by the intended user at all stages of the procedure; and
- reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.

16.3 The devices intended for self-testing shall, where reasonably possible, include a procedure by which the intended user can:

- verify that, at the time of use, the device will perform as intended by the manufacturer; and
- be warned if the device has failed to provide a valid result.

Amendment 206

Proposal for a regulation

Annex I – part III – point 17.1 – introductory part

Text proposed by the Commission

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, taking into account the following:

Amendment

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, ***and must be made available on the manufacturer's website*** taking into account the following:

Amendment 207

Proposal for a regulation

Annex I – point 17.1 – point (vi)

Text proposed by the Commission

(vi) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations,

Amendment

(vi) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations,

contraindications, precautions or warnings in the information supplied by the manufacturer.

precautions or warnings in the information supplied by the manufacturer.

Amendment 208

Proposal for a regulation

Annex I – part III – point 17.2 – point (xv)

Text proposed by the Commission

Amendment

(xv) If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;

deleted

Amendment 209

Proposal for a regulation

Annex I – part III – point 17.3.1 – point (ii) – introductory part

Text proposed by the Commission

Amendment

(ii) The device's intended purpose:

(ii) The device's intended purpose **which may include:**

Amendment 210

Proposal for a regulation

Annex I – part III – point 17.3.1 – point ii – indent 2

Text proposed by the Commission

Amendment

– its function (e.g. screening, monitoring, diagnosis or aid to diagnosis);

– its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, **prognosis, companion diagnostic**);

Amendment 211

Proposal for a regulation

Annex I – part III – point 17.3.1 – point ii – indent 7 a (new)

Text proposed by the Commission

Amendment

- for companion diagnostics, the relevant target population and directions for use with associated therapeutic(s).

Amendment 212

Proposal for a regulation

Annex I – part III – point 17.3.2 – point i a (new)

Text proposed by the Commission

Amendment

(ia) The instruction for use shall be understandable to a layperson and reviewed by the representatives of relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.

Amendment 213

Proposal for a regulation

Annex II – point 1.1 – point c – point ii

Text proposed by the Commission

Amendment

(ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis);

(ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, **prognosis, companion diagnosis**);

Amendment 214

Proposal for a regulation

Annex II – point 1.1 – point c – point viii a (new)

Text proposed by the Commission

Amendment

(viii a) for companion diagnostics, the relevant target population and directions for use with the associated therapeutic(s).

Amendment 265

Proposal for a regulation

Annex II – point 3.2 – point b

Text proposed by the Commission

Amendment

(b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.

(b) identification of all sites, including suppliers and sub-contractors, where **critical** manufacturing activities are performed.

Amendment 215

Proposal for a regulation

Annex II – point 6.2 – paragraph 2

Text proposed by the Commission

The clinical evidence report referred to in Section 3 of Annex XII shall be included and/or fully referenced in the technical documentation.

Amendment

The clinical evidence report referred to in Section 3 of Annex XII shall be included and fully referenced in the technical documentation.

Amendment 266

Proposal for a regulation

Annex III – point 7

Text proposed by the Commission

7. References to the relevant harmonised standards or CTS used in relation to which conformity is declared;

Amendment

deleted

Amendment 216

Proposal for a regulation

Annex V – part A – point 15

Text proposed by the Commission

15. in case of devices classified as class C or D, the summary of safety and performance,

Amendment

15. in case of devices classified as class C or D, the summary of safety and performance, **and the full dataset collected during the clinical study and the post-market clinical follow-up.**

Amendment 217

Proposal for a regulation

Annex V – part A – point 18 a (new)

Text proposed by the Commission

Amendment

18a. Full technical documentation and the clinical performance report.

Amendment 218

Proposal for a regulation

Annex VI - points 1.1.4 and 1.2 to 1.6

1.1. Legal status and organisational structure

1.1. Legal status and organisational structure

1.1.4. The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.

1.1.4. The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.

The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented.

The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented. ***This information shall be made publicly available.***

1.2. Independence and impartiality

1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer.

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer. ***This does not preclude the notified body from performing conformity assessment activities for different economic operators producing different or similar products.***

1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall have procedures in place that effectively ensure identification, investigation and resolution of any case in which a conflict of interests may arise, including involvement in consultancy services in the field of in vitro diagnostic medical devices prior to taking up employment with the notified body.

1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall have procedures in place that effectively ensure identification, investigation and resolution of any case in which a conflict of interests may arise, including involvement in consultancy services in the field of in vitro diagnostic medical devices prior to taking up employment with the notified body.

1.2.3. The notified body, its top-level

1.2.3. The notified body, its top-level

management and the personnel responsible for carrying out the conformity assessment tasks shall not:

- be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;

- be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;

- offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

management and the personnel responsible for carrying out the conformity assessment tasks shall not:

- be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;

- be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;

- offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

The notified body shall make publicly available the declarations of interest of its top-level management and the personnel responsible for carrying out the conformity assessment tasks. The national authority shall verify the compliance of the notified body with the provisions under this point and shall report to the Commission twice a year in full transparency.

1.2.4. The impartiality of the notified bodies, of their top level management *and* of the assessment personnel shall be guaranteed. The remuneration of the top level management *and* assessment personnel of a notified body shall not depend on the results of the assessments.

1.2.5. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests shall be ensured and documented between, on the one hand, the national authority responsible for notified bodies and/or competent authority and, on the other hand, the notified body.

1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities.

1.2.7. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.

1.2.8. The requirements of this section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer seeking their conformity assessment.

1.3. Confidentiality

The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the national authorities responsible for notified bodies, competent

1.2.4. The impartiality of the notified bodies, of their top level management, of the assessment personnel *and subcontractors* shall be guaranteed. The remuneration of the top level management, assessment personnel *and subcontractors* of a notified body shall not depend on the results of the assessments.

1.2.5. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests shall be ensured and documented between, on the one hand, the national authority responsible for notified bodies and/or competent authority and, on the other hand, the notified body.

1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities. *The notified body shall provide evidence to the national authority of compliance with this point.*

1.2.7. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.

1.2.8. The requirements of this section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer seeking their conformity assessment.

1.3. Confidentiality

The personnel of a notified body shall observe professional secrecy with regard to information obtained in carrying out their tasks under this Regulation, *only in justified cases and* except in relation to the national authorities responsible for notified

authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

1.4. Liability

The notified body shall take out appropriate liability insurance that corresponds to the conformity assessment activities for which it is notified, including the possible suspension, restriction or withdrawal of certificates, and the geographic scope of its activities, unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

1.5. Financial requirements

The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.

bodies, competent authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

Where information and data are requested from the notified body by public or healthcare professionals and where such a request is declined, the notified body shall justify the reasons for non-disclosure and shall make publicly available its justification.

1.4. Liability

The notified body shall take out appropriate liability insurance that corresponds to the conformity assessment activities for which it is notified, including the possible suspension, restriction or withdrawal of certificates, and the geographic scope of its activities, unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

1.5. Financial requirements

The notified body, ***including its subsidiaries***, shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel ***including subcontractors, and trained on*** the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, ***standards***, guidance and best practice documents adopted in the framework of this Regulation. ***The notified body shall keep a record of the actions it takes to***

1.6.2. The notified body shall adhere to a code of conduct, addressing among other things, ethical business practices for notified bodies in the field of in vitro diagnostic medical devices that is accepted by the national authorities responsible for notified bodies. The code of conduct shall provide for a mechanism of monitoring and verification of its implementation by notified bodies.

inform its personnel.

1.6.2. The notified body shall adhere to a code of conduct, addressing among other things, ethical business practices for notified bodies in the field of in vitro diagnostic medical devices that is accepted by the national authorities responsible for notified bodies. The code of conduct shall provide for a mechanism of monitoring and verification of its implementation by notified bodies.

Amendment 219

Proposal for a regulation Annex VI - point 2

Text proposed by the Commission

Amendment

2. QUALITY MANAGEMENT REQUIREMENTS

2. QUALITY MANAGEMENT REQUIREMENTS

2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and capable of supporting and demonstrating the consistent achievement of the requirements of this Regulation.

2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and capable of supporting and demonstrating the consistent achievement of the requirements of this Regulation.

2.2. The quality management system of the notified body shall at least address the following:

2.2. The quality management system of the notified body **and its subcontractors** shall at least address the following:

- policies for assignment of personnel to activities and their responsibilities;
- decision-making process in accordance with the tasks, responsibilities and role of the top-level management and other notified body personnel;
- control of documents;
- control of records;
- management review;
- internal audits;
- corrective and preventive actions;
- complaints and appeals.

- policies for assignment of personnel to activities and their responsibilities;
- decision-making process in accordance with the tasks, responsibilities and role of the top-level management and other notified body personnel;
- control of documents;
- control of records;
- management review;
- internal audits;
- corrective and preventive actions;
- complaints and appeals;
- **continuous training.**

Amendment 220

Proposal for a regulation Annex VI - point 3.1

Text proposed by the Commission

3.1.1. A notified body shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

In particular, it shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

This presupposes the availability within its organisation of sufficient scientific personnel who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.

Amendment

3.1.1. A notified body ***and its subcontractors*** shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility. ***In accordance with Article 35, this requirement shall be monitored to ensure that it is of the requisite quality.***

In particular, it shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical, ***scientific*** and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

This presupposes the ***permanent*** availability within its organisation of sufficient scientific personnel who possess experience, ***a university degree*** and ***the*** knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.

Permanent "in house" staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of those experts, as well as their declarations of interest and the specific tasks for which they are responsible.

Notified bodies shall conduct unannounced inspections at least once a year of all premises at which the medical devices coming within their remit are

manufactured.

The notified body responsible for carrying out the assessment tasks shall notify the other Member States of the findings of the annual inspections carried out. Those findings shall be set out in a report.

It shall also forward a record of the annual inspections carried out to the relevant national authority responsible.

3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with technical knowledge and sufficient and appropriate experience relating to *in vitro* diagnostic medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data.

3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with *medical, technical and where needed pharmacological* knowledge and sufficient and appropriate experience relating to *in vitro* diagnostic medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data *or the evaluation of an assessment made by a subcontractor.*

3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel involved in conformity assessment activities and inform the personnel concerned about it.

3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel, *including any subcontractors, subsidiaries and external experts*, involved in conformity assessment activities and inform the personnel concerned about it.

3.1.3a. The notified body shall make available the list of its personnel involved in conformity assessment activities and their expertise to the Commission and, upon request, to other parties. That list shall be kept up to date.

Amendment 221

Proposal for a regulation Annex VI - point 3.2

Text proposed by the Commission

Amendment

3.2.1. The notified body shall establish and document qualification criteria and procedures for selection and authorisation

3.2.1. The **MDCG** shall establish and document *the principles of high level competence and* qualification criteria and

of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas covered by the scope of designation.

3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 31, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, clinical evaluation and the different types of sterilisation processes.

3.2.3. The personnel responsible for authorising other personnel to perform specific conformity assessment activities and the personnel with overall responsibility for the final review and decision-making on certification shall be employed by the notified body itself and shall not be subcontracted. This personnel altogether shall have proven knowledge and experience in the following:

- Union *in vitro* diagnostic medical devices legislation and relevant guidance documents;
- the conformity assessment procedures in accordance with this Regulation;
- a broad base of *in vitro* diagnostic medical device technologies, the *in vitro* diagnostic medical device industry and the design and manufacture of *in vitro* diagnostic medical devices;

procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas covered by the scope of designation.

3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 31, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, *safety*, clinical evaluation and the different types of sterilisation processes.

3.2.3. The personnel responsible for authorising other personnel to perform specific conformity assessment activities and the personnel with overall responsibility for the final review and decision-making on certification shall be employed by the notified body itself and shall not be subcontracted. This personnel altogether shall have proven knowledge and experience in the following:

- Union *in vitro* diagnostic medical devices legislation and relevant guidance documents;
- the conformity assessment procedures in accordance with this Regulation;
- a broad base of *in vitro* diagnostic medical device technologies, the *in vitro* diagnostic medical device industry and the design and manufacture of *in vitro* diagnostic medical devices;

- the notified body's quality management system and related procedures;
- the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to *in vitro* diagnostic medical devices as well as the relevant qualification criteria;
- training relevant to personnel involved in conformity assessment activities in relation to *in vitro* diagnostic medical devices;
- the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.

3.2.4. Notified bodies shall have available personnel with **clinical** expertise. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

- identify when specialist input is required for the assessment of the clinical evaluation conducted by the manufacturer

- the notified body's quality management system and related procedures;
- the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to *in vitro* diagnostic medical devices as well as the relevant qualification criteria;
- training relevant to personnel involved in conformity assessment activities in relation to *in vitro* diagnostic medical devices;
- the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.

- at least three years' appropriate experience in the field of conformity assessments within a notified body,

- adequate seniority / experience in conformity assessments under this Regulation or previously applicable law during a period of at least three years within a notified body. The notified body staff involved in certification decisions shall not have been involved in the conformity assessment on which a certification decision needs to be taken.

3.2.4. ***Clinical experts:*** notified bodies shall have available personnel with expertise ***in clinical investigation design, medical statistics, clinical patient management, Good Clinical Practice in the field of clinical investigations. Permanent "in house" staff shall be used. However, in accordance with Article 28, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of those experts, as well as the specific tasks for which they are responsible.*** This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

- identify when specialist input is required for the assessment of ***the clinical investigation plans and*** the clinical

and identify appropriately qualified experts;

- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;

- be able to discuss *the clinical data contained within the manufacturer's clinical evaluation* with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;

- be able to scientifically challenge the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;

- be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;

- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.

3.2.5. The personnel responsible for carrying out product related review (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, sterilisation, software validation) shall have the following proven qualification:

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g.

evaluation conducted by the manufacturer and identify appropriately qualified experts;

- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;

- be able to discuss *the rationale of the planned study design, the clinical investigation plans and the selection of the control intervention* with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;

- be able to scientifically challenge *the clinical investigation plans and* the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;

- be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;

- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.

- *ensure independence and objectivity and disclose potential conflicts of interest.*

3.2.5. **Product assessors:** the personnel responsible for carrying out product related **reviews** (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, sterilisation, software validation) shall have *specialist qualifications which should include:*

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g.

medicine, natural science or engineering;

- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;

- appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

- appropriate knowledge and experience of risk management and related *in vitro* diagnostic medical device standards and guidance documents;

- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out those assessments

3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality **management** system shall have the following proven qualification:

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering

- four years professional experience in the field of healthcare products or related

medicine, natural science or engineering;

- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device (***as defined within a generic device group***) or technology to be assessed or related to the scientific aspects to be assessed;

- appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

- ***qualification based on technical or scientific fields (e.g. sterilization, biocompatibility, animal tissue, human tissue, software, functional safety, clinical evaluation, electrical safety, packaging);***

- appropriate knowledge and experience of risk management and related *in vitro* diagnostic medical device standards and guidance documents;

- ***appropriate knowledge and experience of clinical evaluation;***

- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out those assessments

3.2.6. **Auditor:** The personnel responsible for carrying out audits of the manufacturer's quality **assurance** system shall have ***specialist qualifications, which should include:***

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering

- four years professional experience in the field of healthcare products or related

sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management

- appropriate knowledge of the *in vitro* diagnostic medical devices legislation as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

- appropriate knowledge and experience of risk management and related *in vitro* diagnostic medical device standards and guidance documents;

- appropriate knowledge of quality management systems and related standards and guidance documents;

- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out the audits;

- training in auditing techniques enabling them to challenge quality management systems.

sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management

- appropriate knowledge of technologies such as those defined by IAF/EAC coding or equivalent;

- appropriate knowledge of the *in vitro* diagnostic medical devices legislation as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

- appropriate knowledge and experience of risk management and related *in vitro* diagnostic medical device standards and guidance documents;

- appropriate knowledge of quality management systems and related standards and guidance documents;

- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out the audits;

- training in auditing techniques enabling them to challenge quality management systems.

Amendment 222

Proposal for a regulation Annex VI - point 3.4

Text proposed by the Commission

3.4. Subcontractors and external experts

3.4.1. Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract clearly defined parts of the conformity assessment activities. The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.

Amendment

3.4. Subcontractors and external experts

3.4.1. Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract clearly defined parts of the conformity assessment activities ***in particular where clinical expertise is limited***. The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.

3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented and be subject to a written agreement covering, among others, confidentiality and conflict of interests.

3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, the notified body shall have adequate own competence in each product area for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.

3.4.4. The notified body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used

3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented, ***be publicly available*** and be subject to a written agreement covering, among others, confidentiality and conflict of interests.

3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, the notified body shall have adequate own competence in each product area, ***each treatment or medical speciality*** for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.

3.4.4. The notified body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used

3.4.4a. The policy and procedures under points 3.4.2 and 3.4.4 shall be communicated to the national authority before any subcontracting takes place.

Amendment 223

Proposal for a regulation Annex VI – point 3.5.2

Text proposed by the Commission

3.5.2. It shall review the competence of its personnel and identify training needs in order to maintain the required level of qualification and knowledge.

Amendment

3.5.2. It shall review the competence of its personnel and identify training needs ***and ensure that necessary measures are taken accordingly***, in order to maintain the required level of qualification and knowledge.

Amendment 224

Proposal for a regulation

Annex VI – point 3.5 a – title and point 3.5 a.1 (new)

Text proposed by the Commission

Amendment

3.5a. Additional requirements for Special Notified Bodies

3.5a.1. Clinical Experts for Special Notified Bodies

Notified bodies shall have available personnel with expertise in clinical investigation design, medical statistics, clinical patient management, Good Clinical Practice in the field of clinical investigations and pharmacology. Permanent "in house" staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of those experts, as well as the specific tasks for which they are responsible. That personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

- identify when specialist input is required for the assessment of the clinical investigation plans and the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;

- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;

- be able to discuss the rationale of the planned study design, the clinical investigation plans and the selection of the control intervention with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment

- of the clinical evaluation;*
- be able to scientifically challenge the clinical investigation plans and the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;*
- be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;*
- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.*
- have an understanding of active substances.*
- ensure independence and objectivity and disclose potential conflicts of interest*

Amendment 267

Proposal for a regulation Annex VI - point 3.5 a.2. (new)

Text proposed by the Commission

Amendment

3.5a.2. Product Specialists for Special Notified Bodies

The personnel responsible for carrying out product related reviews (e.g. design dossier review, technical documentation review or type examination) for devices referred to in Article 41 a shall have the following proven Product Specialist qualification:

- Meet the requirement for Product Assessors;***
- Have an advanced academic degree in a field relevant to medical devices, or alternatively have six years of relevant experience in in vitro diagnostic medical devices or related sectors;***
- Have an ability to identify key risks of products within the specialist's product categories without prior reference to manufacturer's specifications or risk***

analyses;

- Have an ability to assess the essential requirements in the absence of harmonised or established national standards;

- The professional experience should be gained in the first product category their qualification is based on, relevant to the product category of designation of the notified body, providing sufficient knowledge and experience to thoroughly analyse the design, the validation and verification testing and the clinical use, with a sound understanding of the design, manufacture, testing, clinical use and risks associated with such a device;

- Missing professional experience for further product categories closely related to the first product category, may be substituted by internal product specific training programmes;

- For product specialists with qualifications in specific technology, professional experience should be gained in the specific technology area, relevant to the scope of designation of the notified body.

For each designated product category, the Special notify body shall have a minimum of two product specialists of which at least one in house, to review devices referred to in Article 41a(1). For those devices, product specialists shall be available in house for the designated technology fields covered by the scope of notification.

Amendment 226

Proposal for a regulation Annex VI – Point 3.5 a.3. (new)

Text proposed by the Commission

Amendment

3.5a.3. Training for Product Specialists

Product Specialists shall receive a minimum of 36 hours of training in in vitro diagnostic medical devices, in vitro diagnostic medical device regulations, and

assessment and certification principles, including training in the verification of manufactured product.

The Notified Body shall ensure that in order for a product specialist to be qualified, he or she obtains adequate training in the relevant procedures of the Notified Body's quality management system and is taken through a training plan consisting of sufficient design dossier reviews witnessed, performed under supervision and peer reviewed before doing a qualifying full independent review.

For each product category for which qualification is sought, the Notified Body must show evidence of appropriate knowledge in the product category. A minimum of five design dossiers (at least two of them initial applications or significant extensions of certification) shall be conducted for the first product category. For subsequent qualification in additional product categories evidence of adequate product knowledge and experience needs to be demonstrated.

Amendment 227

Proposal for a regulation Annex VI – Point 3.5 a. 4. (new)

Text proposed by the Commission

Amendment

3.5a.4. Maintenance Qualification for Product Specialists

Qualifications of product specialists shall be reviewed on an annual basis; a minimum of four design dossier reviews, independent of the number of product categories qualified for shall be demonstrated as a four-year rolling average. Reviews of significant changes to the approved design (not full design examinations) shall count for 50%, as shall reviews supervised.

On an ongoing basis, the product specialist shall be required to show evidence of state-of-art product

knowledge, review experience in each product category for which qualification exists. Annual training with regard to latest status of Regulations, harmonized standards, relevant guidance documents, clinical evaluation, performance evaluation, CTS requirements must be demonstrated.

If the requirements for renewal of qualification are not met, the qualification shall be suspended. Then the first upcoming design dossier review shall be done under supervision, and re-qualification confirmed based on the outcome of that review.

Amendment 228

Proposal for a regulation Annex VI – point 4

Text proposed by the Commission

4.1. The notified body's decision-making process shall be clearly documented, including the *process for the* issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.

4.2. The notified body shall have in place a documented process for the conduct of the conformity assessment procedures for which it is designated taking into account their respective specificities, including legally required consultations, in respect of the different categories of devices covered by the scope of notification, ensuring transparency and the ability of reproduction of those procedures.

4.3. The notified body shall have in place documented procedures covering at least:

- the application for conformity assessment by a manufacturer or by an authorised representative,

Amendment

4.1. The notified body's decision-making process shall be **transparent and** clearly documented **and its outcome publicly available**, including the issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.

4.2. The notified body shall have in place a documented process for the conduct of the conformity assessment procedures for which it is designated taking into account their respective specificities, including legally required consultations, in respect of the different categories of devices covered by the scope of notification, ensuring transparency and the ability of reproduction of those procedures.

4.3. The notified body shall have in place documented procedures **that are publicly available** covering at least:

- the application for conformity assessment by a manufacturer or by an authorised representative,

- the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as in vitro diagnostic medical device and its classification,
- the language of the application, of the correspondence and of the documentation to be submitted.
- the terms of the agreement with the manufacturer or authorised representative,
- the fees to be charged for conformity assessment activities,
- the assessment of relevant changes to be submitted for prior approval,
- the planning of surveillance,
- the renewal of certificates.

- the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as in vitro diagnostic medical device and its classification, *as well as the recommended duration for conducting its conformity assessment,*
- the language of the application, of the correspondence and of the documentation to be submitted.
- the terms of the agreement with the manufacturer or authorised representative,
- the fees to be charged for conformity assessment activities,
- the assessment of relevant changes to be submitted for prior approval,
- the planning of surveillance,
- the renewal of certificates.

Amendment 229

Proposal for a regulation Annex VI – point 4 a (new)

Text proposed by the Commission

Amendment

4a. A RECOMMENDED DURATION FOR CONFORMITY ASSESSMENTS CONDUCTED BY NOTIFIED BODIES

4.1. Notified bodies shall identify the audit duration for the stage 1 and stage 2 initial audits, and surveillance audits for each applicant and certified client

4.2. An audit duration shall be based, inter alia, on the effective number of personnel of the organisation, the complexity of the processes within the organisation, the nature and the characteristics of the medical devices included in the scope of the audit and the different technologies that are employed to manufacture and control the medical

devices. The audit duration may be adjusted based on any significant factors that uniquely apply to the organisation to be audited. The notified body shall ensure that any variation in audit duration does not compromise the effectiveness of audits.

4.3. The duration of any scheduled on site audit shall not be less than one auditor/day.

4.4. Certification of multiple sites under one quality assurance system shall not be based on a sampling system.

Amendment 230

Proposal for a regulation Annex VII – point 1.1

Text proposed by the Commission

1.1. Application of the classification rules shall be governed by the intended purpose of the devices.

Amendment

1.1. Application of the classification rules shall be governed by the intended purpose, **novelty, complexity and inherent risk** of the devices.

Amendment 231

Proposal for a regulation Annex VII – point 2.3 – point c

Text proposed by the Commission

c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested, or to the individual's offspring;

Amendment

c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or **embryo** being tested, or to the individual's offspring;

Amendment 232

Proposal for a regulation Annex VII – point 2.3 – point f – point ii

Text proposed by the Commission

(ii) Devices intended to be used for disease staging; or

Amendment

(ii) Devices intended to be used for disease staging **or prognosis**; or

Amendment 233

Proposal for a regulation Annex VII – point 2.3 – point j

Text proposed by the Commission

(j) screening for congenital disorders in the foetus.

Amendment

(j) screening for congenital disorders in the foetus **or embryo**.

Amendment 235

Proposal for a regulation Annex VIII – point 3.2 – point d – indent 2

Text proposed by the Commission

- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

Amendment

- the product identification **and traceability** procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

Amendment 236

Proposal for a regulation Annex VIII – point 4.4 – subparagraph 1

Text proposed by the Commission

The notified body shall randomly perform unannounced **factory** inspections **to the manufacturer** and, if appropriate, **at** the manufacturer's suppliers and/or subcontractors, **which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment**. The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer.

Amendment

The notified body shall randomly perform **for each manufacturer and generic device group** unannounced inspections **at the relevant manufacturing sites** and, if appropriate, at the manufacturer's suppliers and/or subcontractors, The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer. **At the time of such inspections, the notified body shall carry out tests or ask to carry them out in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and with a test report. The notified body shall carry out such inspections at least once every three years.**

Amendment 237

Proposal for a regulation

Annex VIII – point 5.3

Text proposed by the Commission

The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

Amendment

The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. ***The notified body shall ensure that the manufacturer's application adequately describes the design, manufacture and performance of the device, allowing assessment of whether the product conforms with the requirements set out in this Regulation. The notified body shall comment on the conformity of the following:***

- general description of the product,***
- design specifications, including a description of the solutions adopted to fulfil the essential requirements,***
- systematic procedures used for the design process and techniques used to control, monitor and verify the design of the device.***

The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

Amendment 238

Proposal for a regulation Annex VIII – point 5.7

Text proposed by the Commission

5.7. To verify conformity of manufactured devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of

Amendment

5.7. To verify conformity of manufactured devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of

manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer, **in regular intervals**, shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests. The reference laboratory shall inform the notified body about its findings.

manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests. The reference laboratory shall inform the notified body about its findings.

Amendment 239

Proposal for a regulation Annex VIII – point 6.1 – title

Text proposed by the Commission

6.1. Examination of the design of devices for self-testing **and near-patient testing** classified as class A, B or C

Amendment

6.1 Examination of the design of devices for self-testing classified as class A, B or C **and of devices for near patient testing classified as class C**

Amendment 240

Proposal for a regulation Annex VIII – point 6.1 – point a

Text proposed by the Commission

(a) The manufacturer of devices for self-testing **or near-patient testing** classified as class A, B and C shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design.

Amendment

(a) The manufacturer of devices for self-testing classified as class A, B and C **and of devices for near patient testing classified as class C** shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design.

Amendment 241

Proposal for a regulation Annex VIII – point 6.2 – point e

Text proposed by the Commission

(e) The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA

Amendment

(e) The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA

when making its decision. It shall **convey its final** decision to the medicinal products competent authority concerned or to the EMA. The design-examination certificate shall be delivered in accordance with point (d) of Section 6.1.

on the scientific suitability of the companion diagnostic when making its decision. **If the notified body deviates from that position,** it shall **justify its** decision to the medicinal products competent authority concerned or to the EMA. **If no agreement is reached, the notified body shall inform the MDCG thereof.** The design-examination certificate shall be delivered in accordance with point (d) of Section 6.1.

Amendment 242

Proposal for a regulation Annex IX – point 3.5

Text proposed by the Commission

3.5. in the case of devices classified as class D, request a reference laboratory, where designated in accordance with Article 78, to verify compliance of the device with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The reference laboratory shall provide a scientific opinion within 30 days. The scientific opinion of the reference laboratory and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable;

Amendment

3.5. in the case of devices classified as class D, **or for companion diagnostics,** request a reference laboratory, where designated in accordance with Article 78, to verify compliance of the device with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The reference laboratory shall provide a scientific opinion within 30 days. The scientific opinion of the reference laboratory and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable;

Amendment 243

Proposal for a regulation Annex IX – point 3.6

Text proposed by the Commission

3.6. For companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product, seek the opinion, on the basis of the draft summary of safety and

Amendment

deleted

performance and the draft instructions for use, of a one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as ‘medicinal products competent authority’) or the European Medicines Agency (hereinafter referred to as ‘EMA’) on the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA. The medicinal products authority or the European Medicines Agency shall deliver its opinion, if any, within 60 days upon receipt of the valid documentation. This 60-day period may be extended only once for a further 60 days on scientifically valid grounds. The opinion of the medicinal products authority or of the EMA and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA when making its decision. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA.

Amendment 244

Proposal for a regulation Annex IX – point 5.4

Text proposed by the Commission

Amendment

5.4. Where the changes affect a companion diagnostic approved through the EU type-examination certificate with regard to its suitability in relation to a medicinal product, the notified body shall consult the medicinal products competent authority that was involved in the initial consultation or the EMA. The medicinal products competent authority or the EMA shall give its opinion, if any, within 30 days after receipt of the valid

deleted

documentation regarding the changes. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.

Amendment 245

Proposal for a regulation Annex X – point 5.1

Text proposed by the Commission

5.1. In the case of devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer, *in regular intervals*, shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests. The reference laboratory shall inform the notified body about its findings

Amendment

5.1. In the case of devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate *laboratory* tests. The reference laboratory shall inform the notified body about its findings

Amendment 246

Proposal for a regulation Annex XII – Part A – point 1.2.1.4

Text proposed by the Commission

1.2.1.4 The analytical performance *data* shall be summarised as part of *the clinical evidence report*.

Amendment

1.2.1.4 The analytical performance *full dataset* shall *accompany the clinical evidence report and may* be summarised as part of *it*.

Amendment 247

Proposal for a regulation Annex XII – Part A – point 1.2.2.5

Text proposed by the Commission

1.2.2.5 Clinical performance *data* shall be summarised as part of *the clinical evidence report*.

Amendment

1.2.2.5 Clinical performance *full dataset* shall *accompany the clinical evidence report and may* be summarised as part of *it*.

Amendment 248

Proposal for a regulation

Annex XII – Part A – point 1.2.2.6 – indent 2

Text proposed by the Commission

– For devices classified as class C according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion and the relevant details of the study protocol;

Amendment

– For devices classified as class C according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion and the relevant details of the study protocol *and the full dataset*;

Amendment 249

Proposal for a regulation

Annex XII – Part A – point 1.2.2.6 – indent 3

Text proposed by the Commission

– For devices classified as class D according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion, the relevant details of the study protocol and the *individual data points*.

Amendment

– For devices classified as class D according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion, the relevant details of the study protocol and the *full dataset*.

Amendment 250

Proposal for a regulation

Annex XII – Part A – point 2.2 – paragraph 1

Text proposed by the Commission

Every step in the clinical performance study, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association

Amendment

Every step in the clinical performance study, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association

Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964 and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008.

Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964 and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008.

Conformity with the above principles shall be granted after an examination by the Ethics Committee concerned.

Amendment 251

Proposal for a regulation

Annex XII – Part A – point 2.3.3 – paragraph 1

Text proposed by the Commission

A 'clinical performance study report', signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study protocol, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale.

Amendment

A 'clinical performance study report', signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study protocol, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale. ***The report shall be accompanied by the clinical evidence report as described in point 3.1 and be accessible through the electronic system referred to in Article 51.***

Amendment 252

Proposal for a regulation

Annex XII – Part A – point 3.3

Text proposed by the Commission

3.3 The clinical evidence and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's post-market surveillance

Amendment

3.3 The clinical evidence ***data*** and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's post-market surveillance

plan referred to in Article 8(5) which shall include a plan for the device post-market follow-up in accordance with Part B of this Annex.

plan referred to in Article 8(5) which shall include a plan for the device post-market follow-up in accordance with Part B of this Annex. ***The clinical evidence data and its subsequent updates through post-market follow-up shall be accessible through the electronic systems referred to in Articles 51 and 60.***

Amendment 253

Proposal for a regulation Annex XIII – Part 1 a (new) – point 1 (new)

Text proposed by the Commission

Amendment

1a. Incapacitated subjects and minors

1. Incapacitated subjects

In the case of incapacitated subjects who have not given, or who have not refused to give, informed consent before the onset of their incapacity, interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies may be conducted only where, in addition to the general conditions, all of the following conditions are met:

- the informed consent of the legal representative has been obtained; consent shall represent the subject's presumed will and may be revoked at any time, without detriment to the subject;***
- the incapacitated subject has received adequate information in relation to his or her capacity for understanding regarding the study and its risks and benefits from the investigator or his/her representative, in accordance with the national law of the Member State concerned;***
- the explicit wish of an incapacitated subject, who is capable of forming an opinion and assessing this information, to refuse participation in, or to be withdrawn from, the clinical performance study at any time without giving a reason and with no liability or prejudice whatsoever being incurred by the subject or their legal representative as a result shall be followed***

by the investigator;

– no incentives or financial inducements are given except compensation for participation in the clinical performance study;

– such research is essential to validate data obtained in a clinical performance study on persons able to give informed consent or by other research methods;

– such research relates directly to a medical condition from which the person concerned suffers;

– the clinical performance study has been designed to minimise pain, discomfort, fear, and any other foreseeable risk in relation to the disease and the developmental stage and both the risk threshold and the degree of distress are specially defined and constantly observed;

- the research is necessary to promote the health of the population concerned by the clinical performance study and cannot instead be performed on capacitated subjects;

– there are grounds for expecting that participation in the clinical performance study will produce a benefit for the incapacitated subject outweighing the risks or will produce only a minimal risk;

– an ethics committee, with expertise regarding the relevant disease and the patient population concerned, or that has taken advice on clinical, ethical and psychosocial questions in the field of the relevant disease and patient population concerned, has endorsed the protocol;

The test subject shall as far as possible take part in the consent procedure.

Amendment 254

Proposal for a regulation

Annex XIII – Part I a (new) - point 2 (new)

Text proposed by the Commission

Amendment

2. Minors

An interventional clinical performance study and other clinical performance studies involving risks for the minor may be conducted only where, in addition to the general conditions, all of the following conditions are met:

– the written informed consent of the legal representative or representatives has been obtained, whereby consent shall represent the minor’s presumed will;

- the informed and express consent of the minor has been obtained, where the minor is able to give consent according to national law,

– the minor has received all relevant information in a way adapted to his or her age and maturity, from a medical doctor (either the investigator or member of the study team) trained or experienced in working with children, regarding the study, the risks and the benefits;

– without prejudice to second indent, the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from, the clinical performance study at any time, is duly taken into consideration by the investigator;

– no incentives or financial inducements are given except payment for participation in the clinical performance study

– such research either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;

– the clinical performance study has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage, and both the risk threshold and the degree of distress are specially defined and constantly observed;

– there are grounds to expect that some direct benefit for the category of patients concerned by the study may be obtained from the clinical performance study;

- the corresponding scientific guidelines of the Agency have been followed;*
- the interests of the patient shall always prevail over those of science and society;*
- the clinical performance study does not replicate other studies based on the same hypothesis and age-appropriate technology is used;*
- an ethics committee, with paediatric expertise or after taking advice in clinical, ethical and psychosocial problems in the field of paediatrics, has endorsed the protocol.*

The minor shall take part in the consent procedure in a manner adapted to his or her age and maturity. Minors who are able to give consent according to national law shall also give their informed and express consent to participate in the study.

If during a clinical performance study the minor reaches the age of majority as defined in the national law of the Member State concerned, his/her express informed consent shall be obtained before the study may continue.